

**OMNIBUS SOLICITATION OF THE  
NATIONAL INSTITUTES OF HEALTH,  
CENTERS FOR DISEASE CONTROL AND PREVENTION, AND  
FOOD AND DRUG ADMINISTRATION FOR**

**SMALL BUSINESS INNOVATION  
RESEARCH (SBIR)**

**AND**

**SMALL BUSINESS TECHNOLOGY  
TRANSFER (STTR)**

**GRANT APPLICATIONS**

**NIH, CDC, and FDA Program Descriptions and  
Research Topics**

**SUBMISSION DATES**

**SEPTEMBER 5, 2024, JANUARY 5, 2025, AND  
APRIL 5, 2025**

**National Institutes of Health (SBIR and STTR)  
Centers for Disease Control and Prevention (SBIR)  
Food and Drug Administration (SBIR)**

Notices of Funding Opportunities, Application Instructions, and Appendices are contained in separate files. Follow the links below to view these documents.

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## NOTICES OF FUNDING OPPORTUNITIES

**REMINDER: ALL APPLICATIONS MUST BE SUBMITTED IN RESPONSE TO A NOTICE OF FUNDING OPPORTUNITY THROUGH GRANTS.GOV**

[PHS 2023-02 OMNIBUS SOLICITATION OF THE NIH, CDC, AND FDA FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS \(PARENT SBIR \[R43/R44\] CLINICAL TRIAL NOT ALLOWED\)](#)

[PHS 2023-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS TECHNOLOGY TRANSFER GRANT APPLICATIONS \(PARENT STTR \[R41/R42\] CLINICAL TRIAL NOT ALLOWED\)](#)

[PHS 2023-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS \(PARENT SBIR \[R43/R44\] CLINICAL TRIAL REQUIRED\)](#)

[PHS 2023-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS TECHNOLOGY TRANSFER GRANT APPLICATIONS \(PARENT STTR \[R41/R42\] CLINICAL TRIAL REQUIRED\)](#)

[ADDITIONAL SPECIAL ANNOUNCEMENTS FOR SMALL BUSINESS RESEARCH OPPORTUNITIES](#)

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## APPLICATION INSTRUCTIONS

[SF424 \(R&R\) APPLICATION INSTRUCTIONS AND ELECTRONIC SUBMISSION INFORMATION](#)

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## PROGRAM DESCRIPTIONS AND RESEARCH GRANT TOPICS

The research topics shown in this solicitation represent program areas that may be of interest to small businesses and fall within the missions of the NIH, CDC, and FDA. Small businesses are encouraged to submit SBIR and STTR grant applications in these areas. Grant applications will be accepted and considered in any area within the mission of the awarding components (i.e., Institutes and Centers (ICs)) identified in this solicitation. Information about the HHS SBIR and STTR programs for applicants and awardees, including resources and programs available to HHS SBIR and STTR awardees, can be found at <https://seed.nih.gov/>.

Applicants are strongly encouraged to subscribe to the [NIH Guide for Grants and Contracts LISTSERV](#) or query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, and FDA awarding components.

You may also subscribe to the [SBIR-STTR LISTSERV](#) to get timely information about the NIH SBIR and STTR Programs.

Additional information on each of the awarding components (ICs) and their research interests is available electronically on the home pages shown throughout the “Research Topics” section of the solicitation.

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### NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

The goals of the agency are as follows:

1. to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
2. to develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
3. to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
4. to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

in the causes, diagnosis, prevention, and cure of human diseases;  
in the processes of human growth and development;  
in the biological effects of environmental contaminants;  
in the understanding of mental, addictive and physical disorders; and  
in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

In addition, the NIH sponsors training of research personnel; career development of new and established scientists; construction and renovation of research facilities and provision of other research resources. Information about the NIH SBIR and STTR programs for applicants and awardees, including resources

and programs available to NIH SBIR and STTR awardees, can be found at <https://seed.nih.gov/support-for-small-businesses>.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes and Centers). Those components that have an extramural element, that is, those that provide funds for research and research training activities in organizations external to the NIH, are shown below. The NIH makes every effort to finance worthy applications, including the co-funding of such applications by one or more awarding components having relevance in the projects.

Total funding support (direct costs, indirect costs, fees) normally may not exceed \$306,872 for Phase I awards and \$2,045,816 for the duration of the Phase II awards. However, this amount is subject to change and the most current information can be found on the [NIH SEED website](#). Awards exceeding these amounts may be made at the discretion of an Institute or Center for applications within one of the [SBA-Approved Waiver Topics](#). Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Center staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of Institute or Center priorities, constraints on the growth of average grant costs, and the availability of funds.

Before considering and/or preparing an application to the SBIR and STTR programs, all applicants are **strongly encouraged** to review the agencies' and NIH Institutes' and Centers' websites and to contact the SBIR and STTR program coordinators listed below. The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR and STTR program.

### **Contact Information**

Questions of a general nature about the HHS SBIR and STTR program may be directed to:

SEED (Small business Education and Entrepreneurial Development)

Email: [SEEDinfo@nih.gov](mailto:SEEDinfo@nih.gov)

For Agency, Institute and Center Scientific/Research (Program) and Financial/Grants Management contacts, please see the [contact page](#)

## **NATIONAL INSTITUTE ON AGING (NIA)**

### **Mission**

NIA's mission is to:

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging.
- Foster the development of research and clinician-scientists in aging.
- Provide research resources.
- Disseminate information about aging and advances in research to the public, health care professionals, and the scientific community, among a variety of audiences.

### **Strategic Directions for Research**

<https://www.nia.nih.gov/about/aging-strategic-directions-research>

### **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#), unless the application fits an SBA-approved NIA waiver topic. For topics listed in the [SBA-Approved Waiver Topics](#), the NIA generally will not fund Phase I applications to the Omnibus greater than \$400,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,250,000 total costs or project periods greater than 3 years.

However, if your application is AD/ADRD focused, you may come in at \$500,000 for Phase I and \$2,500,000 for Phase II (total costs). For budgetary, administrative, or programmatic reasons, the NIA may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

### **Specific SBIR and STTR Program Information**

The NIA SBIR-STTR Programs support research and product development focusing on aging and aging-related conditions and diseases, as well as other problems and needs unique to older Americans. NIA supports SBIR and STTR research and product development under four divisions: Behavioral and Social Research, Biology of Aging (Aging Biology), Geriatrics and Clinical Gerontology, and Neuroscience.

**The NIA will consider any application relevant to the NIA's mission, even if it does not directly address one of the topics below.** For additional information about NIA's SBIR and STTR programs please visit: <https://www.nia.nih.gov/research/osbr>

### **Specific Funding Opportunities and Programs**

In addition to this Omnibus program announcement, the NIA releases targeted Notices of Funding Opportunities (NOFOs) throughout the year. These NOFOs are listed to inform potential applicants about other funding opportunities to which they can apply; applications submitted in response to this Omnibus program announcement are not limited to research and development areas described in the following targeted NOFOs. NOFOs may specify specific budget caps that are above the caps listed for Omnibus applications. Applicants are encouraged to visit the following webpage for an up to date list of NIA SBIR/STTR funding opportunities: <https://www.nia.nih.gov/research/nia-small-business-funding-opportunities>.

For projects that aim to address Alzheimer's Disease and Related Dementias, applicants are encouraged to consider the following funding opportunities which allows Phase I budgets up to \$500,000 and Phase II budgets up to \$2.5M (for topics covered by the approved waiver from SBA):

- Advanced Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional): Accepts Phase I, Phase II, Direct-to-Phase II and fast-track applications. Details can be found here <https://grants.nih.gov/grants/guide/pa-files/pas-22-196.html>
- Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42 Clinical Trial Optional): Accepts Phase I, Phase II, and fast-track applications. Details can be found here: <https://grants.nih.gov/grants/guide/pa-files/PAS-22-197.html>

**Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIA welcomes submission of Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing a wide range of aging-focused products, including digital- mobile/cyber-health technology, pharmaceutical compounds, and medical devices. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to realize further progress in commercialization, including stimulating interest in and investment by third parties. NIA will generally not fund Phase IIBs greater than \$3M total costs.

Prospective Phase IIB Competing Renewal applicants are strongly encouraged to contact NIA's SBIR-STTR program contact prior to consideration and preparation of a Phase IIB application and well in advance of the SBIR-STTR submission due dates.

NIA also welcomes the submission of CRP applications to the 2 CRP NOFOs (and subsequent reissued NOFOs):

- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Not Allowed ([PAR-23-219](#))
- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Required ([PAR-23-220](#))

**Clinical Trials**

Does NIA accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NIA accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	<ul style="list-style-type: none"> <li>• Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42 Clinical Trial Optional) (<a href="#">PAS-22-197</a>)</li> <li>• Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional) (<a href="#">PAS-22-196</a>)</li> </ul>



Does NIA support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<p>NOFOs include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Alzheimer's Drug-Development Program (U01 Clinical Trial Optional) (<a href="#">PAR-22-047</a>)</li> <li>• Blueprint Neurotherapeutics Network (BPN): Biologic-based Drug Discovery and Development for Disorders of the Nervous System (UG3/UH3 Clinical Trial Optional) (<a href="#">PAR-21-163</a>)</li> <li>• Early and Late Stage Clinical Trials for the Spectrum of Alzheimer's Disease/Alzheimer's Related Dementias and Age-Related Cognitive Decline (R01 Clinical Trial Optional) (<a href="#">PAR-23-081</a>)</li> <li>• Pilot Studies for the Spectrum of Alzheimer's Disease/Alzheimer's Disease-Related Dementias and Age-Related Cognitive Decline (R61 Clinical Trial Optional) (<a href="#">PAR-23-083</a>)</li> <li>• Seamless Early-Stage Clinical Drug Development (Phase 1 to 2a) for Novel therapeutic Agents for the Spectrum of Alzheimer's Disease (AD) and AD-related Dementias (ARD) (UG3/UH3 Clinical Trial Required) (<a href="#">PAR 23 274</a>)</li> <li>• Alzheimer's Clinical Trials Consortium (ACTC) Clinical Trials (R01 Clinical Trial Required) (<a href="#">PAR 20 309</a>)</li> </ul>
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## Research Topics

The NIA will consider any application relevant to the NIA's mission, even if it does not directly address one of the topics below. The below topics provide an overview of interest areas for both non-clinical trial and clinical trial applications.

- A. Alzheimer's Disease (AD), AD-Related Dementias (ARD), and Age-Related Change in Brain Function.** Research and development of novel interventions to ameliorate AD/ARD; improve AD/ARD care; or further the understanding of the etiology of AD/ARD, neurodegeneration, brain connectivity, neuroplasticity, or brain— behavior relationships. This includes drug and non-drug interventions for age-related cognitive decline, delirium, sleep disorders, or other central nervous system dysfunctions, including dysfunctions of the motor, emotional, sensory, and neuroimmune systems. This also includes novel biomarkers of neural stem cell functions and new technologies or imaging devices that improve or study brain connectivity; metabolism; sleep; or cognitive, motor, emotional, or sensory activity.
- a. For projects addressing AD/ARD, you may want to consider applying to [PAS-22-196](#) (SBIR) and [PAS-22-197](#) (STTR), which have higher budget limits.
- B. Aging in Place of Choice.** Research and development of social, behavioral, and environmental interventions that promote independence and aging in place by addressing the unique needs of older adults, their healthcare providers, and caregivers. This includes prosthetics, assistive devices and robotics, digital technologies and software, and technology to mitigate age-related physical and behavioral health challenges or to improve healthcare delivery, care coordination,

and disease management.

- C. **Age-Related Diseases and Conditions.** Research and development of new diagnostic tools and methods, biomarkers, therapeutics, imaging devices, and technologies to monitor, diagnose, predict, prevent, treat, and further the understanding of the molecular mechanisms of aging or age-related diseases and conditions.
- D. **Research Tools.** Development and validation of innovative tools, resources, or methodologies that promote the efficient, cost-effective, and high-quality collection, analysis, or interpretation of aging-related quantitative or qualitative data. This includes bioinformatics tools; screening platforms; surveying, sampling, and behavioral/behavioral economics methods; and clinical instruments to enhance the study of aging, cellular resiliencies, and aging-related diseases.

### **Special Areas of Interest**

Areas of particular interest related to aging biology, aging-related diseases and conditions, behavioral health, and AD/DRD include, but are not limited to the following:

- A. Companion diagnostics and other forms of personalized medicine.
- B. Bioinformatics, public health informatics, or data science technologies/methods (e.g., machine learning, artificial intelligence) to better understand aging biology and/or predict health outcomes.
- C. Novel cell and gene therapies, as well as other novel therapeutic approaches to AD/DRD.
- D. Biomarkers and diagnostic tools for the early detection of disease.
- E. Prevention and therapeutics that directly target mechanisms related to aging biology.
- F. Assistive technology, devices, and mobile applications for older adults and caregivers.
- G. Tools, technologies, and analytic methods to address health disparities among older adults and/or biological determinants of health disparities.

### **Contact Information**

For more information on research topics and questions about potential NIA SBIR/STTR grant applications and NIA's participation in the Phase IIB or CRP programs, please contact:

#### **Program Contacts, NIA Small Business R & D Programs:**

Michael-David ("M-D") A.R.R.Kerns, M.M., M.S., Ph.D.

National Institute on Aging (NIA)

Email: [niasmallbusiness@mail.nih.gov](mailto:niasmallbusiness@mail.nih.gov)

Bio: <https://www.nia.nih.gov/about/staff/kerns-michael-david>

#### **Rajesh Kumar, Ph.D.**

National Institute on Aging (NIA) Email:

[niasmallbusiness@mail.nih.gov](mailto:niasmallbusiness@mail.nih.gov)

If there are specific questions pertaining to the interests or activities of the NIA scientific divisions, contact:

**Division of Aging Biology:**

Leonid Tsap, Ph.D.

National Institute on Aging (NIA)

Email: [Leonid.Tsap@nih.gov](mailto:Leonid.Tsap@nih.gov)

Bio: <https://www.nia.nih.gov/about/staff/tsap-leonid>

**Division of Behavioral and Social Research:**

Dinesh John, Ph.D.

National Institute on Aging (NIA)

Email: [dinesh.john@nih.gov](mailto:dinesh.john@nih.gov)

Bio: <https://www.nia.nih.gov/about/staff/john-dinesh>

**Division of Geriatrics and Clinical Gerontology:**

Lyndon Joseph, Ph.D.

National Institute on Aging (NIA)

Telephone: 301-496-6761

Email: [lyndon.joseph@nih.gov](mailto:lyndon.joseph@nih.gov)

Bio: <https://www.nia.nih.gov/about/staff/joseph-lyndon>

**Division of Neuroscience:**

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Bio: <https://www.nia.nih.gov/about/staff/martin-jones-zane>

# NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

## **Mission**

NIAAA supports research on the causes, prevention, control, and treatment of the major health problems associated with alcohol misuse. NIAAA supports research on the causes, prevention, control, and treatment of the major health problems associated with alcohol misuse. Through its extramural research programs, NIAAA funds a wide range of basic and applied research to develop new and/or improved technologies and approaches for increasing the effectiveness of diagnosis, treatment, and prevention of Alcohol Use Disorder (AUD) and alcohol-related health complications. NIAAA also desires to strengthen research dissemination, scientific communications, public education, and data collection activities in the areas of its research priorities.

Studies that examine racial, ethnic, and gender minorities as well as other underserved populations that experience more negative alcohol-related consequences of illness and premature death than the general population are highly encouraged and sought.

## **Budget Guidance**

NIAAA will make awards compliant with all statutory guidelines as outlined above. Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the Small Business Administration (SBA), which can be found on the [NIH SEED website](#). With the exception of the topics indicated therein, NIAAA will generally not fund Phase I applications to the Omnibus greater than \$385K or Phase II awards over \$3M total costs even if topics are listed under the [SBA-Approved Waiver Topics](#). Applicants considering a requested budget greater than the standard limits are strongly encouraged to contact the [NIAAA SBIR/STTR Program Director](#) before submitting an application. For budgetary, administrative, or programmatic reasons, NIAAA may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application.

## **Specific Funding Opportunities and Programs**

In addition to the Omnibus program announcement, NIAAA has targeted Notices of Funding Opportunities (NOFOs). Please visit our [NIAAA SBIR/STTR program webpage](#) to view the latest targeted NOFOs.

NIAAA Phase I grantees may consider applying for the I-Corps at NIH pilot program ([PA-22-073](#)).

## **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIAAA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to, medical implants, drugs, vaccines, biologicals, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. To be eligible for Phase IIB consideration, the project must retain high significance in the light of current market conditions.

Prospective applicants are strongly encouraged to contact NIH staff well in advance of submitting a Phase IIB Competing Renewal application by submitting to [niaasbirsttr@mail.nih.gov](mailto:niaasbirsttr@mail.nih.gov) a letter of intent that includes the following information:

- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Grant number and title
- Progress of the Phase II award
- Goals and justification for the Phase IIB request

It is expected that only a portion of NIAAA SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

NIAAA will accept submission of CRP applications to the following NOFOs (and reissues):

- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late-Stage Development - Clinical Trial Not Allowed ([PAR-23-219](#))
- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late-Stage Development - Clinical Trial Required ([PAR-23-220](#))

### **Clinical Trials**

Does NIAAA accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NIAAA accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	<a href="https://www.niaaa.nih.gov/research/niaaa-sbir/funding-opportunities">https://www.niaaa.nih.gov/research/niaaa-sbir/funding-opportunities</a>
Does NIAAA support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<a href="https://niaaa.nih.gov/grant-funding/funding-opportunities">https://niaaa.nih.gov/grant-funding/funding-opportunities</a>

### **Research Topics**

The topics listed below reflect examples of NIAAA’s program priorities at the time of the NIH Omnibus solicitation and *should not be considered all-inclusive*. NIAAA will consider **ALL applications** relevant to NIAAA’s mission. The topics below include areas of interest for both pre-clinical and clinical research.

#### **BASIC SCIENCE**

Through basic scientific research, great strides have been made in understanding the mechanisms by which alcohol exerts its effects on human health and behavior. New tools, techniques, paradigms, and technology are needed to enable researchers to further understand the underlying biological and behavioral mechanisms through which conditions associated with AUD develop.

#### **Research Tools/Technologies/Devices**

1. Induced pluripotent stem cells (iPS), including disease specific cell lines and gene-edited models (e.g., alcohol-related organ damage and disease with human iPS cell-derived organoids) and from adult-derived human iPSCs cells representing genetic variations in alcohol metabolism (e.g., alcohol dehydrogenase (ADH), aldehyde dehydrogenase (ALDH), cytochrome P450 isozyme CYP2E1, and glutathione S-transferase (GST)) or models of normal development and alterations by prenatal alcohol exposure, and embryonic stem cell models of development and effects of alcohol exposure.
2. Novel technologies to measure and interpret non-coding RNA (ncRNA) gene expression, following alcohol exposure, in the brain at the cellular level or in non-animal research models.
3. Using single-cell transcriptomics and multiomics technologies and sequencing to reveal the molecular fingerprint of cell states and their predicted signaling circuits in tissues across development and AUD.
4. Tools to detect dynamic and concurrent changes of neurotransmitters and neuromodulators in the brain of behaving animals.
5. Tools to detect the effects of alcohol on the central nervous system (CNS) structure and activity.

6. Novel animal models, including transgenic animals.
7. Hepatocyte cell line capable of maintaining viability and metabolic functions in culture systems for an indefinite period.
8. Experimental systems that mimic organ function.
9. New methods of ethanol administration to animals that produce precise dose control or that closely mimic types of alcohol exposure occurring in humans.
10. New ligands that will enhance the potential usefulness of PET and SPECT neuroimaging technologies for the study of the etiology of AUD and related brain pathology.
11. Humanized animal models to study AUD in different organ systems.
12. Methods to detect epigenetic changes as disease drivers due to metabolic reprogramming by alcohol.
13. Tools to determine the prevalence of alcohol associated organ diseases: alcoholic cardiomyopathy, sarcopenia, pancreatitis, pulmonary, immune and bone diseases.
14. Optoelectronics probes and devices used to manipulate nerve cell activity in awake animals to better study nerve cell function in the body's periphery.
15. Generate organoids from iPSCs that specifically model sleep-regulating brain regions affected by alcohol, providing a platform for studying alcohol's neurobiological impacts on sleep at the organ level.

## **PREVENTION/TREATMENT/RECOVERY**

Prevention strategies/programs and educational services, behavioral treatment programs, medications, and digital health technologies are crucial in ameliorating the negative health effects and consequences associated with AUD and alcohol misuse and recovery.

### **Medications Development**

1. Preclinical and/or clinical development of therapeutics for AUD and alcohol-related complications (e.g., craving, sleep problems, withdrawal symptoms, and negative affect).
2. Early therapeutic discovery activities (e.g., target ID, lead compound target validation).
3. Investigational New Drug (IND)-enabling studies.
4. Extended formulations or reformulations of existing medications that improve efficacy or compliance.
5. Therapeutics for individuals with co-occurring health conditions, such as post-traumatic stress disorder (PTSD), HIV, alcoholic hepatitis, liver fibrosis, cirrhosis, pancreatitis, cardiomyopathy, or other alcohol-induced tissue damage.
6. Development of precision medicine tools (e.g., biomarker panel) to predict treatment outcomes among AUD patients.

### **Programs or Therapies to Prevent or Treat AUD and/or the Consequences of Alcohol Misuse, Hazardous Drinking, and AUD Across the Lifespan**

1. Novel behavioral health or educational programs aimed at preventing or treating AUD or associated consequences of AUD, alcohol misuse, or hazardous drinking across the life span.

2. Prevention or treatment programs tailored specifically to the needs of the following groups: children of individuals with AUD, women, racial and ethnic underrepresented populations, sexual and gender minority populations, individuals with Fetal Alcohol Spectrum Disorders (FASD) across the lifespan, persons with disabilities, adolescents/young adults, the elderly, individuals in rural settings, individuals with psychiatric comorbidities (e.g., PTSD, major depressive disorder, etc.).
3. Computerized versions of empirically supported prevention or treatment programs, including but not limited to in languages other than English.
4. Prevention curricula, videos, multi-media programs, and training materials for use with adolescents and other population groups and in the NIAAA priority areas.
5. Therapeutic, skill-building, and educational program products that enhance behavioral, neurocognitive, social, adaptive, and motor function to improve the overall well-being of individuals with FASD and their families.
6. Therapies to mitigate alcohol-associated adverse impact on the development of liver and/or lung diseases.
7. Strategies and methods to increase awareness and salience among high-risk groups of the tragic consequences of driving after drinking.
8. Therapies or programs specifically focused on sustaining mid- and long-term recovery from AUD.

**Digital Health Tools (mHealth, health IT, wearable devices, telehealth, telemedicine, and personalized medicine)**

1. Wearable Alcohol Biosensor - minimally invasive, near real-time detection, remote monitoring, infrared or other non-sweat based technology preferred.
2. Validation of promising technologies, biosensors, and research tools.
3. Development of precision medicine tools to predict an individual's risk for developing AUD and/or quantify progression to an AUD diagnosis.
4. Tools to improve the prevention or treatment of AUD and alcohol-related problems.
5. Applications that facilitate long-term recovery support and improve continued engagement in recovery support services.
6. Tools to improve the identification and diagnosis of FASD and prenatal alcohol exposure.
7. Applications or tools to improve medication safety (e.g., multiple medications, interactions with alcohol).
8. Mobile device applications or other health technologies to improve the effectiveness, accessibility, and use of behavioral interventions for AUD and co-occurring disorders, including HIV.
9. Solutions or applications to improve minority health and health disparities with capabilities of reaching persons in rural, remote, and under-resourced/under-served communities.
10. Virtual reality (VR) technology to create immersive environments that simulate real-world scenarios involving alcohol consumption and its effects on behavior and sleep, for understanding environmental and social factors in AUD.
11. Non-invasive, wearable devices capable of monitoring physiological and biochemical markers of alcohol intake and its impact on sleep patterns in real-time, utilizing technologies like bioimpedance.
12. App-based digital platforms that offer personalized cognitive-behavioral therapy for

insomnia (CBT-I) and other sleep improvement techniques for individuals with AUD, integrating wearable sleep data.

## **DIAGNOSTICS**

Improving the current battery or developing new approaches to measurement, diagnosis, and assessment of the severity of AUD, alcohol misuse and health consequences, FASD, and alcohol-related organ damage.

### **Imaging Examination Technologies for Early and Precise Diagnosis of Alcohol-Related Organ Damage**

#### **Biomarkers for AUD and alcohol-related health effects**

1. Detection (e.g., biochemical, unbiased assay) of alcohol intake for extended period (e.g., 2 weeks, 2 months) after drinking episode.
2. Signatures of alcohol-induced organ damage and familial risk.
3. Reduction of time to results for current assays (e.g., phosphatidylethanol (Peth), ethyl glucuronide (EtG)).
4. Increase accuracy of alcohol intake detection by developing a novel combination of biomarkers (e.g., PEth, EtG)).
5. Improve assay methodologies for established biomarkers of alcohol consumption considering cost, timeliness, and accessibility in a range of clinical settings.
6. Point of care devices, for use in rural or remote primary care and hospital settings.
7. Validation of promising biomarkers that can be used to improve clinical research and practice (for example, diagnosis, prognosis, and treatment response) for alcohol related health conditions, including AUD, FASD, and alcohol associated organ injury.
8. Tools or kits to measure aristolochic acid (AA)-adducts and advanced glycation end products (AGEs) in serum, cerebral spinal fluid, and brain and other organs impacted by AUD in animal models and pre-clinical settings including their relationship to the biomarkers of neuro- inflammation.
9. Tools to detect alcohol-induced damage in those patients with HIV infection or co-infection.
10. Measurement and integration of 'omics data for AUD and alcohol-related organ damage.

## **DATA SCIENCE**

Software and tools can be used for discovery of new biomarkers and targets, precision medicine, and other applications to increase the efficiency and efficacy of treating AUD and alcohol-related health effects.

### **Data Science Tools**

1. Algorithms for integrative analysis incorporating multiple current NIAAA supported (current and legacy), government, and public datasets, including machine learning, deep learning, artificial intelligence, data mining and other model based and model-free approaches.
2. Software applications for data interfaces for aggregation, imputation, harmonization, or visualization of data from multiple sources, including current and future NIH data systems.
3. Algorithms and/or software tools for improving data collection, i.e., smart phone apps, extraction of specific alcohol research parameters from existing large databases and established public health studies, biological sensors or wearable



devices.

4. Computational and/or systems biology models of alcohol exposure, tolerance, and resilience.
5. Computational, statistical or bioinformatics tools to organize and manage high throughput data obtained by genomic, functional genomic, or other 'omic strategies.
6. Computational tools to combine multiple data modalities (e.g., omics, imaging).
7. Application of machine learning and artificial intelligence, including large language models, in alcohol research, including ethics and privacy concerns.
8. Translation of 'omics' data into clinically relevant predictions and outcomes for AUD and alcohol- related organ damage.

### **Contact Information**

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# NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

## Mission

NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. Read more about the NIAID Mission [at our website](#).

## Budget Guidance

Total funding support (direct costs, indirect costs, fee) normally may not exceed the dollar amounts specified by the SBA, which can be found on the [NIH SEED website](#). Budget requests at or near these hard caps should be well justified. Phase II/IIB applicants should note that NIAID **will not** generally allow awards (of any duration) that exceed \$1,000,000 total costs per year.

NIH has received a waiver from SBA, as authorized by statute, to exceed total award amount hard caps for specific topics. The current list of approved NIAID topics is included in the [SBA-Approved Waiver Topics](#). Topics that align with NIAID's priority research areas are listed for each Division; any listed NIAID topic is sufficient to consider budget requests that exceed the hard caps. Budget requests exceeding the hard caps must be very well justified in the "Budget Justification" attachment to the Research and Related Budget form and be clearly consistent with the scope of the proposal.

For proposals that address an approved topic, NIAID will allow Phase I applications with budgets of up to \$300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to \$1,000,000 total costs per year for up to 3 years. Requests for these budget levels must be very well-justified. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

NIAID staff cannot provide prior approval to exceed hard caps. Compliance with a pre-approved topic will be confirmed at time of award by the applicant's Grants Management Specialist and Program Officer.

NIAID will consider well justified Technical and Business Assistance (TABAs) costs up to the limits specified on the [NIH SEED Website](#). These costs can be requested *in addition* to the Phase I and II limits indicated above.

NIAID will generally not make SBIR or STTR awards with budgets that exceed these guidelines. For budgetary, administrative, or programmatic reasons, NIAID may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

## Specific SBIR and STTR Program Information

NIAID's Division of AIDS (**DAIDS**), Division of Allergy, Immunology, and Transplantation (**DAIT**), and Division of Microbiology and Infectious Diseases (**DMID**) encourage SBIR/STTR applications related to their mission and activities as described below. Questions regarding specific research areas may be addressed to the NIAID Program Officials listed below. General questions about the NIAID SBIR and STTR programs or administrative and business management concerns may be directed to the [NIAID Small Business Program Team](#).

When possible, *applicants are encouraged to use email* for communication.

For information about NIAID's Small Business Programs, please visit [our website](#).

## **Specific Funding Opportunities and Programs**

Targeted Funding Opportunities and Notices of Special of Interest can be reviewed on the [NIAID website](#). However, NIAID welcomes all Phase I and II proposals (except clinical trials) for research that is consistent with our Mission through the SBIR and STTR Omnibus Solicitations [Clinical Trial Not Allowed].

### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIAID welcomes Phase IIB Competing Renewal Applications (**SBIR only**) for Phase II grants and contracts via the Omnibus Solicitation for SBIR Grant Applications, and as indicated by other NIAID Notices of Funding Opportunities (NOFOs). Standard NIAID Phase II funding policy applies unless otherwise stated in the NOFO. STTR Phase II awardees may apply but must switch programs to SBIR. Non-NIAID Phase II awardees must contact NIAID prior to submission to confirm programmatic interest.

NIAID welcomes CRP applications from eligible NIAID Phase II/IB awardees through [PAR-20-129](#) (and subsequent reissued NOFOs) Please review this Notice of Funding Opportunity for details.

### **Clinical Trials**

Does NIAID accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No	
Does NIAID accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44): <a href="https://grants.nih.gov/grants/guide/pa-files/PAR-21-082.html">https://grants.nih.gov/grants/guide/pa-files/PAR-21-082.html</a> (and subsequent reissued NOFOs)
Does NIAID support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	NIAID Clinical Trial Implementation Cooperative Agreement (U01): <a href="https://grants.nih.gov/grants/guide/pa-files/PAR-21-083.html">https://grants.nih.gov/grants/guide/pa-files/PAR-21-083.html</a> (and subsequent reissued NOFOs)  NIH Research Project Grant (Parent R01 Clinical Trial Required): <a href="https://grants.nih.gov/grants/guide/pa-files/PA-20-183.html">https://grants.nih.gov/grants/guide/pa-files/PA-20-183.html</a> (low risk clinical trial proposals, <b>only</b> )

NIAID will generally consider clinical trial proposals consistent with the research topics listed below. However, applicants are strongly encouraged to consult with NIAID Program Staff at least 10 weeks before the receipt date.

**For further information, please consult NIAID's Investigator-Initiated Clinical Trial Resources page:** <https://www.niaid.nih.gov/grants-contracts/investigator-initiated-clinical-trial-resources>

### **Research Topics**

#### **Division of AIDS (DAIDS)**

The Division of AIDS (DAIDS) supports a global research portfolio to advance biological knowledge of HIV/AIDS, its related co-infections, and co-morbidities. With the ultimate goal of creating an "AIDS-Free Generation," the division develops and supports the infrastructure and biomedical research needed to: 1) Reduce HIV incidence through the development of effective biomedical

prevention strategies, including vaccines that are safe and desirable, 2) Develop novel approaches for the treatment and cure of HIV infection, 3) Develop interventions to treat and/or prevent co-infections and co-morbidities of greatest significance, and 4) Engage scientific and community stakeholders to equitably implement effective interventions.

### **Basic Sciences Program**

Supports basic and applied research on the causes, diagnosis, treatment, and prevention of HIV and AIDS.

- A. ***Epidemiology Branch.*** Population-based research, modeling, and comparative effectiveness studies (not including clinical trials) that assess the natural history, biologic, and clinical course of HIV/AIDS, and related outcomes, and could advance treatment and prevention of HIV. Specific interests include phylodynamics and other factors related to HIV transmission and associated biological and behavioral factors, basic research on immunology, virology, and antiretroviral therapy, issues surrounding care for HIV and other co-morbidities, interactions and impact on clinical outcomes. Development of novel electronic tools, including devices and computer programs to enhance behaviors, such as treatment adherence or uptake of treatment guidelines, is also of interest.
- B. ***Pathogenesis & Basic Research Branch.*** Innovative technologies for at-home self-testing to directly detect HIV during the earliest stages of acute infection (before antibody response) or to detect viral rebound following long-term suppression of viremia. Identification and validation of new targets for discovery or design of strategies to prevent HIV transmission, inhibit replication, control viremia in the absence of antiretroviral drugs, or eradicate reservoirs of HIV that persist despite long-term antiretroviral therapy. Innovative approaches for predicting post-treatment immunologic control of viral rebound or for monitoring changes in the size of the rebound-competent HIV reservoir. Determination of atomic structures relevant to HIV prevention, treatment, or cure.
- C. ***Targeted Interventions Branch.*** Discovery and development of small molecule inhibitors with novel or underexplored mechanisms of action using standard and high-throughput technologies; cell-based and gene therapies; RNA-based therapeutics; next-generation biologics; novel targeting and delivery vehicles for agents active against HIV; therapeutic vaccines and monoclonal antibodies; protein chemistry-based anti-HIV approaches; assays to quantitate latent virus; animal models to facilitate evaluation of agents to treat or cure HIV infection.

### **Vaccine Research Program**

Supports the discovery, development and clinical evaluation of an HIV/AIDS vaccine.

- A. ***Vaccine Clinical Research Branch.*** Research areas: (1) phase I, II, and III domestic and international clinical trials of candidate AIDS and TB vaccines and anti-HIV antibodies; (2) evaluation and characterization of immune responses, virologic markers, and improved diagnostic approaches in HIV-infected and uninfected immunized volunteers, and (3) technologies and methods to improve clinical efficacy or reduce the burden of vaccine or monoclonal antibody administration.
- B. ***Preclinical Research and Development Branch.*** Preclinical research to assess and overcome specific biomedical obstacles in HIV vaccine discovery, especially by application of innovative technologies, and/or by the development and supply of novel reagents/resources useful for advancing original vaccine platforms including monoclonal antibody discovery and development for prevention of HIV infection.
- C. ***Vaccine Translational Research Branch.*** VTRB enables research by advancing innovative vaccine concepts and scalable unit operations into the development of cGMP manufactured products. VTRB's efforts to accelerate the development of preventive HIV-1 vaccines involves identifying, supporting and advancing: (a) cell line development to increase Env expression,

production, quality, and yield; (b) evaluation of phase-appropriate upstream and downstream manufacturing processes; (c) scalable and prototype process development and purification platforms; (d) cGMP manufacturing of broad portfolio of vaccine products ranging from complex HIV Env protein immunogens, nanoparticle-based vaccines, viral vectors, virus-like particles (VLP), nucleic acid-based vaccines (DNA and mRNA), monoclonal antibodies for testing in early phase human clinical trials; (e) manufacturing new and/or alternative adjuvant analogs with similar agonist functions as those currently available for optimal immune response; (f) novel and emerging nanoparticle antigen and adjuvant delivery modalities and dosage forms, coformulation technologies and platforms for immunization; (g) antigen-adjuvant formulation development, analytics development to support product characterization, in-process operations, release, and stability testing; and (h) preclinical safety, immunogenicity, and toxicology testing.

### **Therapeutics Research Program**

Develops and oversees research and development of therapies for HIV disease, including complications, co-infections and co-morbidities, in adults.

A. **Drug Development and Preclinical Research Branch.** Basic, preclinical, and translational research for development of new therapies for HIV and HIV-associated co-infections, including *Mycobacterium tuberculosis* and viral hepatitis; development of safer, more efficacious antiviral, antimicrobial, and immune-based therapies, and combinations thereof, including long-acting/extended-release approaches; target identification and validation for HIV-related co-infections and assay development for screening potential therapeutics; preclinical research to elucidate the biology of HIV-related co-infections, including pathogenesis, immune protection and control, and persistence and latency; maintenance of a database of potential anti-infectives for HIV and HIV-related coinfections.

B. **Laboratory and Clinical Sciences Branch.** Research focused on biomarker discovery/validation and assay development for diagnostics, including development and evaluation of practical and affordable tests to measure viral load, drug toxicities, and drug resistance for clinical use; development and testing of new or improved methodologies for diagnosing, monitoring, and following patients under treatment, including tests to detect early infection in seropositive HIV-infected adult and pediatric individuals in poor resource settings; clinical development of laboratory assays; clinical immunology, virology, and pharmacology related to the design and conduct of clinical trials; management of quality assurance contracts for oversight of the quality of clinical laboratory testing in support of clinical trials.

C. **HIV Research Branch.** Clinical research in adults to evaluate chemotherapeutic and immune-based interventions to treat acute and chronic HIV infection and approaches to achieve sustained remission or cure; strategies to augment HIV-specific immune responses and general host immunity to control or clear HIV infection.

D. **Complications & Co-Infections Research Branch.** Clinical research in adults to evaluate new or improved therapies and related strategies for the treatment and/or prevention of HIV-related co-infections (exclusive of *Mycobacterium tuberculosis*) and non-infectious co-morbidities, including Immune Reconstitution Inflammatory Syndrome (IRIS), in people living with HIV.

E. **Tuberculosis Clinical Research Branch.** Clinical research in adults to evaluate therapeutics, therapeutic vaccines and strategies to prevent disease recurrence for tuberculosis in people living with HIV, including those with additional medical conditions that may affect disease outcomes; clinical trials with a primary objective to elucidate the pathophysiology and immunopathogenesis of HIV/TB co-infection including the study of co-infection interactions and changes in the course, pathology, treatment responses, and outcome of either infection.

## Prevention Science Program

Develops and oversees research and development of 1) non-vaccine biomedical HIV prevention strategies in adolescents and adults, and 2) therapies for cure, management, treatment and prevention of HIV and HIV-associated complications in pregnant women, infants, children, and adolescents, including pediatric-friendly formulations. Supports domestic and international phase I, II, and III clinical trials to evaluate these prevention or therapeutic strategies in relevant populations.

- A. ***Preclinical Microbicides and Prevention Research Branch.*** Development of non-vaccine biomedical HIV prevention products including topical microbicides, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and multipurpose prevention technologies (MPT). Emphasis on drug delivery systems (DDS) designed to achieve systemic protection for  $\geq 3$  months. Development of shorter-duration products (i.e., minimum of 7 days to  $<3$  months), which address a compelling specific public health need. Key populations are adolescents, cisgender women, men who have sex with men (MSM), and transgender people.
- B. ***Clinical Prevention Research Branch.*** Development of safe and effective non-vaccine biomedical and integrated HIV prevention interventions to reduce the number of new HIV infections in adults and adolescents. Support the development of HIV incidence assays, biomarkers of adherence, mathematical modeling, and other tools needed to accomplish these objectives. Clinical development of topical microbicides to prevent HIV infection with the goal to advance safe, effective, and acceptable microbicide products toward licensure.
- C. ***Maternal, Adolescent and Pediatric Medicine Branch.*** Therapies for cure, management, treatment and prevention of HIV and HIV-associated complications including TB, in pregnant women, infants, children, and adolescents, including development of pediatric-friendly formulations. Strategies to reduce transmission of HIV and HIV co-infections from mother to child.

## Division of Allergy, Immunology, and Transplantation (DAIT)

The Division of Allergy, Immunology, and Transplantation (DAIT) supports studies of the immune system in health and the cause, pathogenesis, diagnosis, prevention, and treatment of disease caused by immune dysfunction.

- A. ***Allergy, Asthma and Airway Biology Branch.*** Conditions of interest: asthma, food allergy, eosinophilic esophagitis and gastroenteritis in relation to food allergy, atopic dermatitis, urticaria, rhinitis, rhinosinusitis, drug allergy, sepsis. The Branch supports basic and clinical studies investigating mechanisms of disease and new approaches to diagnose, treat or prevent these conditions. Special interest for SBIR/STTR includes a) the development of biomarkers as diagnostic markers, markers of disease severity and predictive markers for treatment effectiveness, particularly of immunologic interventions such as allergen immunotherapy for food and respiratory allergy; b) the development of new forms of allergen immunotherapy aiming at increased tolerogenic immune responses and decreased allergenicity.
- B. ***Basic Immunology Branch.*** The Branch supports basic and clinical research in the following areas: adjuvant discovery and development; origin, maturation, and interactions of immune cells; immune cell receptors, and ligands; cytokine biology; molecular basis of immune activation, antigen recognition, and immune tolerance; immune response regulation; hematopoiesis and stem cell biology; computational immunology; immunologic mechanisms associated with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome; assessment and analysis of vaccine effectiveness in neonates, pregnant women, and adults, and basic immunology of vaccines and immunotherapeutics as medical

countermeasures for biodefense. Special interests for SBIR/STTRs include: adjuvant discovery, development, production of biosimilars, and/or head-to-head comparisons; bioinformatics tools for immune epitope predictions/visualization, and/or for the analysis of multi-parameter or systems immunology data; development and validation of immunologic reagents for analysis of immunity in non-mammalian (e.g., *Xenopus laevis*, zebrafish, *C. elegans*) and under-represented mammalian (e.g., pig, ferret, cow, sheep, bat) models, and development of novel/improved sample sparing methods to analyze human immune responses from limited amounts of human sample (tissue, cells, serum, etc.).

- C. Autoimmunity and Mucosal Immunology Branch.** Preclinical and clinical research to develop and improve the diagnosis and treatment of autoimmune diseases and primary immune deficiencies/inborn errors of immunity (not HIV); basic research of autoimmune disease mechanisms and biomarkers; immunotherapy of disease processes; disorders mediated by lymphocyte products; and discovery and/or development of reagents and other tools for analysis of mucosal immunity.
- D. Transplantation Branch.** Preclinical and clinical research in organ, vascularized composite tissue and cellular transplantation: acute and chronic graft rejection, allogeneic and xenogeneic transplantation, development of immunomodulatory agents to prevent and treat graft rejection and to promote acute and long term graft acceptance and immunologic tolerance, genomics of the alloimmune response, graft versus host disease for hematopoietic stem cell transplantation, minor histocompatibility antigens, complications of immunosuppression in transplantation, and major histocompatibility complex (MHC) region genomics, technologies for MHC typing, and clinical applications of high-resolution HLA typing.
- E. Radiation and Nuclear Countermeasures Program (RNCP).** The RNCP will consider preclinical research to support product development activities leading to interactions with the Food and Drug Administration (FDA). Approaches could include those used to diagnose, mitigate, and/or treat acute or delayed effects of radiation exposure resulting from a radiological or nuclear incident. It is anticipated that in most cases, approval will occur in accordance with the FDA Animal Rule ([21 CFR 314.600 Subpart I](#) for drug products and [21 CFR 601.90 Subpart H](#) for biologic products).

Proposed activities could include:

- Animal model studies or *ex vivo* approaches (e.g., human tissue chips) to confirm/optimize product efficacy;
- Mechanism of action studies needed for FDA consideration;
- Good Laboratory Practice (GLP)/non-GLP pharmacology/toxicology/pharmacokinetics/pharmacodynamics;
- GLP pilot animal efficacy studies;
- Good Manufacturing Practice product scale-up and stability studies;
- Biomarker and biodosimetry assay/device development to determine radiation dose and/or the biological impact of radiation exposure (*in vivo* and *ex vivo* models acceptable).

Priority areas of product development include:

- Approaches targeting organ systems/microbiota, for which no treatments are available (e.g., gastrointestinal, lung, kidney, cardiac, vascular, and skin);
- Approaches to mitigate and/or treat radiation injury given 24 hours or later post-irradiation;
- Minimally invasive, predictive radiation markers, diagnostics and devices for biodosimetry;

- Radionuclide decorporation agents.

## **Division of Microbiology and Infectious Diseases (DMID)**

The Division of Microbiology and Infectious Diseases (DMID) supports research to better understand, treat, and ultimately prevent infectious diseases caused by virtually all infectious agents, except HIV. DMID supports a broad spectrum of research from basic molecular structure, microbial physiology, and pathogenesis, to the development of new and improved vaccines, therapeutics, and vector control measures. DMID also supports medical diagnostics research, which is defined as research to improve the quality of patient assessment and care that would result in the implementation of appropriate therapeutic or preventive measures. In addition, DMID supports studies to better understand mechanisms of pathogen transmission that may include environmental factors. DMID does not support research directed at decontamination or the development of environmentally oriented detectors, whose primary purpose is the identification of specific agents in the environment. Note that some of the organisms and toxins listed below are considered NIAID priority pathogens or toxins for biodefense and emerging infectious disease research.

### ***A. Bacteriology and Mycology Branch.***

The branch oversees research and product development related to:

- Bacterial infections with emphasis on hospital-associated pathogens, including *Acinetobacter*, *Klebsiella*, *Serratia*, *Legionella*, *Pseudomonas*, *Aeromonas*, *Enterobacter*, *Proteus*, non-enteric *E. coli*, staphylococci, enterococci, actinomycetes among others;
- Bacterial zoonoses, including plague, anthrax, tularemia, glanders, melioidosis, Lyme disease, borrelial relapsing fevers, rickettsial diseases, anaplasmosis, ehrlichiosis, bartonellosis, scrubtyphus, Q fever, and leptospirosis;
- Fungal infections including those caused by *Candida*, *Aspergillus*, *Cryptococcus*, *Coccidioides*, *Histoplasma*, *Blastomyces*, *Pneumocystis*, *Microsporidia*, and other pathogenic fungi.

Research is encouraged in the following general areas: (1) vaccines, adjuvants, therapeutics and diagnostics (including target identification and characterization, device or apparatus development, novel delivery, and preclinical evaluation); (2) strategies to combat antibacterial and antifungal drug resistance; (3) applied proteomics and genomics; (4) host-pathogen interactions, including pathogenesis and host response; (5) genetics, molecular, and cell biology; and (6) microbial structure and function.

Research on all of the above is welcome, but the following areas are of particular interest to the branch:

- Vaccines, therapeutics, and medical diagnostics for hospital infections
- Adjunctive therapies and non-traditional approaches to combat and treat antimicrobial resistance
- Diagnostics for invasive fungal diseases
- Novel approaches for the diagnosis of Lyme disease
- Vaccines against *Coccidioidomycosis*

### ***B. Enteric and Sexually Transmitted Infections Branch.***

#### **Enteric Section:**

Enteric Infections Section research portfolios focus on enteric bacterial pathogens, their toxins,



and their infectious diseases; related sequela; and the gastrointestinal microbiota and microbiome.

Special emphasis areas include but are not limited to those below:

- Development of vaccines to prevent bacterial enteric diseases, to protect against neurotoxins and enterotoxins, and to combat enteric diseases in vulnerable populations.
- Development of therapeutics that focus on novel targets, that target toxin activities, and that treat recurrent diseases.
- Development of live biotherapeutic products to restore colonization resistance to enteric pathogens, to combat recurrent or chronic enteric disease, and to restore host immunity against enteric pathogens.
- Development of adjunctive therapies and non-traditional approaches to treat resistant bacteria and to combat further development of antibacterial resistance.
- Development of rapid diagnostics to identify multiple pathogens and their antimicrobial resistance profiles that are appropriate for use in low-resource, outbreaks, and clinical settings, as well as diagnostic approaches that differentiate asymptomatic colonization from infection.

### **Sexually Transmitted Infections Section:**

Areas of emphasis include the development of medical diagnostics including better and more rapid multiplex point of care tests, ability to rapidly determine antibiotic sensitivity, and novel technologies enabling testing in low resource settings while maintaining high sensitivity/specificity; development of new classes of antimicrobials and non-antimicrobial treatment approaches, particularly those focused on reducing the development of antibiotic resistance; novel delivery systems for multipurpose prevention technologies, vaccines and therapeutics for Sexually Transmitted Infections (STIs) and other reproductive tract syndromes such as bacterial vaginosis and pelvic inflammatory disease; understanding vaginal ecology and immunology and approaches to developing synthetic microbiota for use as biotherapeutics or as adjunct therapy to antibiotic treatment; development of epidemiologic and behavioral strategies to reduce transmission of STIs; developing and evaluating interventions and products to better serve adolescents, medically underserved populations, and minority groups who are disproportionately affected by STIs; development of multipurpose prevention technologies to prevent STIs, HIV, and unintended pregnancies; better understanding of the role of STIs in infertility, premature birth, and adverse outcomes of pregnancy and how to improve outcomes; and better understanding of the role of STIs in HIV transmission and the role of HIV in altering the natural history of STIs.

### **C. Respiratory Diseases Branch.**

Research areas include: (1) viral respiratory diseases caused by influenza viruses, human coronaviruses including SARS, MERS, and novel emerging coronaviruses, rhinoviruses, respiratory syncytial virus and other related pneumoviruses and paramyxoviruses; (2) mycobacterial diseases, including tuberculosis (TB) caused by bacteria of the *Mycobacterium tuberculosis* complex, leprosy, Buruli ulcer and non-tuberculous mycobacterial (NTM) diseases, particularly pulmonary infections in persons not afflicted with HIV/AIDS; (3) other bacterial respiratory diseases including bacterial pneumonia primarily caused by *Streptococcus pneumoniae*, *Pseudomonas aeruginosa*, and *Haemophilus influenzae*, pertussis, Group A and B streptococcal diseases, meningitis, upper respiratory infections, acute exacerbations of chronic obstructive pulmonary disease, and cystic fibrosis; and (4) mixed viral/bacterial respiratory infections.

Special emphasis areas include:

- Development of new or improved antimicrobials (especially for antimicrobial-resistant pathogens) and antivirals, including immunotherapeutics, immunomodulators, and host-directed therapies to augment anti-infectives;
- New or improved vaccines (with and without adjuvants);
- Improved delivery systems and formulations for drugs/vaccines;
- Microbial and host biomarkers and biosignatures suitable for diagnostic tests;
- Development of novel or improved diagnostic tools for detection of infection and drug resistance, including rapid point of care diagnostics and quantitation of pathogen in response to therapy;
- Diagnostics to distinguish viral from bacterial infections.

There is particular need for preventive and treatment countermeasures for influenza, including universal vaccine platforms and broad-spectrum antivirals; for novel treatment of respiratory syncytial virus (RSV) and related pneumovirus and paramyxovirus infections; for next generation vaccines, therapeutics, and diagnostics for the prevention and treatment of COVID-19, including pan-coronavirus approaches; for diagnostics including diagnostics for pediatric populations, novel therapeutics, and vaccines (including adjuvants) against *Mycobacterium tuberculosis* (TB); for relevant diagnostics, preventive and curative interventions against non-HIV associated pulmonary Non-tuberculous mycobacteria (NTM); and for the prevention, diagnosis, and treatment of *Bordetella pertussis*, Group A streptococcus, and *Streptococcus pneumoniae* infections and other antibacterial resistant infections.

#### ***D. Parasitology and International Programs Branch.***

Research areas: (1) protozoan infections, including amebiasis, cryptosporidiosis, cyclosporiasis, giardiasis, leishmaniasis, malaria, trypanosomiasis, toxoplasmosis; helminth infections, including cysticercosis, echinococcosis, lymphatic filariasis, schistosomiasis, onchocerciasis, others (e.g., roundworms, tapeworms, and flukes); invertebrate vectors/ectoparasites responsible for human disease (e.g., mosquitoes, black flies, sandflies, tsetse flies, ticks, triatomine bugs, fleas, lice, mites), and selected intermediate hosts of parasites (e.g., snails); (2) parasite biology (genetics, genomics, physiology, molecular biology, and biochemistry); (3) protective immunity, immunopathogenesis, and evasion of host defense; (4) clinical, epidemiological, and natural history studies of parasitic diseases; (5) research and development of vaccines, drugs, immunotherapeutics and immunoprophylaxis, and medical diagnostics; and (6) vector biology and management/control and mechanisms of pathogen transmissions.

Research on the above is welcome, but research on the following is of particular interest to the branch:

- New drug discovery or re-purposing of existing drugs to prevent infection and/or transmission, or to treat parasitic diseases
- Highly sensitive and specific diagnostics tools for parasitic diseases
- Vaccines and vaccine technologies, monoclonal antibodies, and other immune-mediated interventions applicable to prevention or elimination of parasitic diseases
- Technologies or approaches that address arthropod vector monitoring, management, and control, to prevent transmission of vector-borne pathogens to humans

#### ***E. Virology Branch.***

The Virology Branch focuses on:

- a. Acute viral infections caused by arthropod-borne (e.g., mosquito, tick-borne) and rodent-borne viruses, including: dengue, zika, west nile, Japanese encephalitis, chikungunya, yellow fever, hanta, crimean-congo hemorrhagic fever (CCHF), hantavirus, severe fever with thrombocytopenia syndrome (SFTS), heartland, bourbon, tick-borne encephalitis (TBE), powassan, lacrosse, cache valley, rift valley fever, punta toro, andes, sin nombre, hantavirus; viruses causing hemorrhagic fevers: ebola, lassa, junin, venezuelan equine encephalitis (VEE), etc.; and other viruses, including nipah, hendra, measles, polio, coxsackie, enterovirus, pox, rabies, rubella, astrovirus, calicivirus, and rotavirus; pathogen X
- b. Persistent viral infections caused by viruses including adenovirus, bornavirus, coronavirus, herpesvirus, human T-lymphotropic virus, human papillomavirus, parvovirus, and human polyoma virus (JC, BK, and emerging);
- c. Acute infections with hepatitis viruses A, B, C, D and E (HAV, HBV, HCV, HDV, and HEV); chronic infections with hepatitis viruses, B, C, D and E;
- d. Transmissible Spongiform Encephalopathies (TSE)

Areas of emphasis for SBIR/STTR applications include:

- Development of vaccines and vaccine platforms;
- Development of techniques to improve vaccine stability;
- Approaches to identify antiviral targets and agents;
- Chemical design and synthesis of novel antiviral agents;
- Development of therapeutic, prophylactic, and postexposure prophylactic interventions;
- Development and validation of point of care assays for disease diagnosis and to measure response to therapy;
- Development of new preclinical animal model systems that predict clinical efficacy of vaccines, therapeutics and diagnostics.

The Virology Branch does not support applications covering environmental detection and decontamination.

### **Office of Genomics and Advanced Technologies**

The Office of Genomics and Advanced Technologies focuses on broad-based research that emphasizes the development and improvement of high-throughput and large-scale genomics and other advanced technologies for the understanding of infectious diseases and the development of multiplex platforms for medical diagnostics. The technological scope encompasses genomics, genomic epidemiology, phylogenomics, functional genomics, proteomics, metabolomics, glycomics, structural biology, systems biology, computational biology, bioinformatics, and diagnostics, usually across multiple pathogens or pathogen groups.

The goal of our program is (1) to support large-scale experiments using omics, structural and computational biology approaches, (2) to deepen the comprehension of pathogen-host interactions and (3) to accelerate the discovery of innovative diagnostics, vaccines, and therapeutics for infectious diseases. Our program supports the advancement of technologies and platforms that are pathogen-independent or address multiple pathogens and may include sample preparation, instrumentation, and instrument validation.

Special emphasis areas include:

- Development and advancement of genomic, phylogenomic, proteomic, metabolomic, glycomic, structural biology and related technologies for infectious diseases, including single-cell omics technologies and platforms;
- Development of bioinformatic and computational biology, including artificial intelligence/machine learning methods and tools to advance infectious disease research; and
- Development of modeling and bioinformatic tools to integrate omics data that supports the development of vaccines, therapeutics and diagnostics.

### **Office of Biodefense Research and Surety (OBRS)**

The Office of Biodefense Research and Surety (OBRS) supports and oversees a trans-NIH research portfolio to advance discovery and early development of medical countermeasures (MCMs) against chemical threats. To learn more about OBRS and its leadership role in chemical countermeasures research at the NIH, see [NIH CCRP: A Collaborative Opportunity to Develop Effective and Accessible Chemical Medical Countermeasures for the American People](#), published in the Wiley journal Drug Development Research.

### **Biodefense Research Countermeasures Branch (BRCB)**

The Chemical Countermeasures Research Program ([CCRP](#)) supports preclinical basic and applied research towards understanding acute and long-term chronic toxicity resulting from exposure to Department of Homeland Security-designated Chemicals of Concern (CoC) and early development of MCMs to prevent mortality and serious morbidities. The ideal MCM should have rapid post-exposure efficacy, is easily administered in a mass casualty situation (likely by first responders in personal protective equipment) and is widely accessible in the community.

The specific injuries caused by toxic chemical exposure often manifest similarly to conditions observed in conventional clinical practice, such as acute lung injury, acute respiratory distress syndrome, coagulopathy, tissue fibrosis, keratopathy, neovascularization, seizure, and neurodegeneration. As such, "treat the symptom" projects aiming to repurpose already FDA-approved products or those in late-stage development for a conventional clinical indication are highly encouraged.

Areas of Emphasis include but not limited to:

- **Pulmonary Agents:** Development of MCMs to prevent and treat acute and/or chronic lung injury (including edema, capillary leak, and fibrosis) resulting from exposure to agents such as sulfur mustard, chlorine, acrolein, and phosgene.
- **Ultra-Potent Synthetic (UPS) Opioids:** Development of MCMs to treat life-threatening respiratory depression caused by acute intoxication. Treatments should be fast-acting and effective against a variety of synthetic UPS opioids such as fentanyl, carfentanil, and related analogs, and have a mechanism of action different from existing opioid receptor antagonists.
- **Vesicants:** Development of MCMs that mitigates dermal, ocular, and/or systemic (including myelosuppression) toxicities after exposure to chemicals such as sulfur mustard, nitrogen mustard, Lewisite, phosgene oxime. Candidate MCM(s) with the potential to prevent or ameliorate chronic effects such as keratopathy is encouraged.
- **Blood/Cellular Respiration Agents:** Development of MCMs to treat metabolic dysfunction and/or coagulopathy resulting from exposure to agents such cyanide, hydrogen sulfide, and brodifacoum. Candidate cyanide and hydrogen sulfide MCM(s) should also be effective against smoke inhalation-related exposure.
- **Nerve Agents and Organophosphorus (OP) Pesticides:** Development of MCMs to treat

acute muscarinic and nicotinic toxicities, including benzodiazepine refractory seizures, after exposure to agents such as sarin, soman, and VX.

OBRS does not support research directed at diagnostic device development, decontamination, or the development of environmentally oriented detectors, whose primary purpose is the identification of specific chemicals in the environment.

### **Contact Information**

For more information on NIAID's SBIR/STTR research topics, program policy or to identify NIAID Subject Matter Experts for a specific topic, please contact:

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### **Division of AIDS**

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**Office of Biodefense Research and Surety (OBRS)**

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# NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

## **Mission**

The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.

For additional information about areas of interest to NIAMS, please visit the NIAMS Strategic Plan at <https://www.niams.nih.gov/about-niams/strategic-plan-fiscal-years-2020-2024>.

## **Budget Guidance**

For budgetary, administrative, or programmatic reasons, NIAMS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#).

For topics listed in the [SBA-Approved Waiver Topics](#), the NIAMS does not apply these topics to the Omnibus Program Announcements. The NIAMS only applies the waiver topics to special Notices of Funding Opportunities that specifically allow higher budgets than those in the Omnibus Program Announcements. When the waiver topics are applied, NIAMS generally will not fund Phase I applications greater than \$350,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,300,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

NIAMS provides Technical and Business Assistance (TABAs) Funding. Small Businesses may request up to \$6,500 per year for a Phase I and up to \$50,000 per Phase II project (across all years) to support subcontracts or consultants above the budget cap. Small businesses should include this budget request as part of the application and provide a detailed budget justification.

## **Specific SBIR and STTR Program Information**

NIAMS does not participate in the SBIR/STTR clinical trial funding opportunities. NIAMS NON-SBIR/STTR clinical trial funding opportunities support all research within the NIAMS mission areas. It is not the intent of NIAMS to support clinical trials through the SBIR/STTR mechanism. Applicants who wish to submit clinical trials applications to the NIAMS are encouraged to utilize one of the NIAMS NOFOs listed at <https://www.niams.nih.gov/grants-funding/conducting-clinical-research/investigator-clinical-trial-policies>.

## **Specific Funding Opportunities and Programs**

NIAMS has published the SBIR funding opportunity [PAR-23-032](#) promote the translation of academic/non-profit lab research results to marketplace. In addition, the NIAMS participates in funding opportunities for the SBIR/STTR HEAL initiative, the Administrative Supplements to Promote Diversity in Research and Development, and the Small Business

Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health. For currently active Notices of Funding Opportunities, please contact the program staff.

**Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIAMS does not accept Phase IIB renewal applications. NIAMS participates in the CRP program and sets its own budget limits for the CRP applications in the program announcements. NIAMS does not support clinical trials through the CRP program.

**Clinical Trials**

Does NIAMS accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No	
Does NIAMS accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does NIAMS support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<a href="https://www.niams.nih.gov/grants-funding/conducting-clinical-research/investigator-clinical-trial-policies">https://www.niams.nih.gov/grants-funding/conducting-clinical-research/investigator-clinical-trial-policies</a>

**Research Topics**

The NIAMS small business program supports research and development of products and services for prevention, diagnosis and treatment of rheumatic, musculoskeletal and skin diseases. The research topics include, but are not limited to, the following:

- A. ***Rheumatic Diseases.*** The NIAMS supports research on rheumatic and related diseases including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), Lyme arthritis, viral arthritis, gout, calcium pyrophosphate deposition disease (CPDD), spondyloarthropathies, and systemic autoimmune diseases such as systemic lupus erythematosus (SLE), systemic sclerosis (SSc), and autoimmune myositis.
- B. ***Musculoskeletal Diseases.*** The musculoskeletal system is composed of the skeleton, the muscles, and connective tissues such as cartilage, tendon, and ligament. The NIAMS supports research aimed at improving the diagnosis, treatment, and prevention of diseases and injuries of the musculoskeletal system and its component tissues. The topics in this area include research on musculoskeletal diseases such as osteoporosis, osteoarthritis, muscular dystrophy, and osteogenesis imperfecta, tissue engineered products, orthopedic devices and implants, and sports medicine and fitness.
- C. ***Skin Diseases.*** The NIAMS supports research on a wide range of skin diseases and conditions including chronic inflammatory skin diseases such as psoriasis, rosacea, acne vulgaris, and atopic dermatitis and autoimmune diseases such as pemphigus, vitiligo, and alopecia areata. The NIAMS also supports research on skin repair and regeneration in treatment of chronic wounds and reducing scar formation. Skin cancer is an area of overlap with the National Cancer Institute (NCI), with the NIAMS focus on the response of keratinocytes to UV light and early stages in the development of non-melanoma skin cancer and products for prevention of melanocyte tumorigenesis.

This is not an inclusive list of all research topics covered by the NIAMS. To learn more, please visit the NIAMS supported scientific areas at <https://www.niams.nih.gov/grants-funding/funding-opportunities/supported-scientific-areas>

### **Research Topics of High Program Priority**

NIAMS supports all Research and Development activities within its mission. Particular areas of programmatic interest relative to small business initiatives include, but are not limited to:

- A. Innovative research on women's health in the areas of musculoskeletal, rheumatic and skin diseases
- B. Innovative research on health disparity in the areas of musculoskeletal, rheumatic and skin diseases
- C. Innovative diagnostic technology for improving outcomes for maternal health in NIAMS mission areas
- D. Innovative research on rare musculoskeletal, rheumatic and skin diseases
- E. Multiplex assay development for arthritis and musculoskeletal and skin diseases
- F. Lab to marketplace: translation of scientific discoveries in NIAMS mission areas from labs into products on the market
- G. Test and/or validation of novel, state-of-the-art candidate biomarker platforms for predicting the onset and progression of inflammatory diseases of interest to the NIAMS and for determining the pharmacodynamics, safety and/or efficacy of therapeutic agents targeting those diseases.

### **Research Topics of Lower Program Priority**

The general purpose of the SBIR/STTR program is to stimulate technological innovation and increase private sector commercialization of innovations. Due to budget constraints, NIAMS will consider the following research topics a lower program priority:

- Research on a product or a technology to show equivalence to existing products
- A product or a technology has been well funded for more than 10 years, but has not shown any progress towards clinical testing
- A research topic on which multiple similar technologies have been funded and have shown scientific success

### **Contact Information**

For general SBIR/STTR program information, contact: Dr. Xibin Wang, NIAMS SBIR/STTR Coordinator  
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# NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

## Mission

The mission of the [National Institute of Biomedical Imaging and Bioengineering \(NIBIB\)](#) is to transform through technology development, our understanding of disease and its prevention, detection, diagnosis, and treatment. NIBIB supports new tools and technologies to improve human health within its internal laboratories and through grants, collaborations, and training.

## Budget Guidance

- Normally, total funding support (direct costs, indirect costs, fees) may **not** exceed the amounts defined by the Small Business Administration (SBA), which can be found on the [NIH SEED website](#).
- Applicants considering a requested budget greater than the current SBA guidelines should ensure that the project falls within a topic listed in the [SBA-Approved Waiver Topics](#).
- Generally, NIBIB will **not** support Phase I (R41/R43) project periods greater than 1 year, or Phase II (R42/R44) project periods greater than 2 years.
- For budgetary, administrative, or programmatic reasons, NIBIB may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

## Specific SBIR and STTR Program Information

- NIBIB does **not** typically support Phase II STTRs. Applicants interested in submitting a Phase II application should consider the SBIR program and contact program staff at least one month before the application deadline.
- NIBIB does **not** accept Phase IIB renewal applications through the omnibus solicitations.
- NIBIB will accept applications for support of early-stage clinical trials (see [NOT-21-005](#)) in any of the [scientific program areas](#) within NIBIB's mission.

**Applicants are strongly encouraged to contact program staff at [NIBIB-SBIR@mail.nih.gov](mailto:NIBIB-SBIR@mail.nih.gov) at least one month before submitting an application.**

## Specific Funding Opportunities and Programs

- [NIBIB Concept to Clinic: Commercializing Innovation \(C3i\) Program:](#)  
The C3i Program is designed to provide medical device innovators with specialized business frameworks and essential tools for successful translation of biomedical technologies from the lab (concept) to the market (clinic). Through this program, the NIH fosters the development and commercialization of early-stage biomedical technologies by engaging investigators who are interested in better understanding the value of their innovation in addressing an unmet market need. The curriculum and customized mentoring provided by the C3i Program are intended to guide investigators as they assess the commercial viability and potential business opportunity for their innovation.
- Targeted Funding Opportunities and Notices of Special of Interest can be reviewed on the [NIBIB website](#).

## Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

- NIBIB does **not** accept Phase IIB renewal application through the omnibus solicitations.
- NIBIB participates in the [Commercialization Readiness Pilot \(CRP\)](#) program for **Phase II applications only**.

## **Clinical Trials**

Does NIBIB accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	See <a href="#">NOT-21-005</a> for NIBIB Clinical Trial Funding Information
Does NIBIB accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	See <a href="#">NOT-21-005</a> for NIBIB Clinical Trial Funding Information
Does NIBIB support Clinical Trials through Non-SBIR/STTR Notices of Funding Opportunities?	Yes	See <a href="#">NOT-21-005</a> for NIBIB Clinical Trial Funding Information

## **Research Topics**

- A. [Bio-Electromagnetic Technologies](#). Development of technologies that use static or dynamic electromagnetic fields for sensing, imaging, or therapeutic effects. The emphasis is on increasing the sensitivity, spatial/temporal resolution, efficacy, or safety of bioelectromagnetic devices through the development of novel hardware, method of operation, or pre-/post-processing techniques for single modalities or the combination of multiple modalities. This program may support the development of magnetic particle imaging, electrical impedance tomography, electroencephalography, magnetoencephalography, electromagnetic-field-induced hyperthermia/ablation, and microwave/terahertz imaging, for example.
- B. [Bioanalytical Sensors](#). Development of sensor technologies for the detection and quantitation of clinically relevant analytes in complex matrices for use in biomedical applications. Emphasis is on engineering the components and functionality of bioanalytical sensors. Detection could be based on optical, chemical, electrochemical, and/or physical (such as mechanical, gravimetric, thermal) perturbation of a sample, for example. Examples of technologies of interest include, but are not limited to, nano-textured substrates for analyte detection, DNA sensors for liquid biopsy, and small molecule detectors for diagnosing infectious diseases.
- C. [Image-Guided Interventions](#). Development of novel image-directed technologies for guidance, navigation, tissue differentiation, and disease identification for reaching specified targets during therapeutic procedures, which may range along the continuum from non-invasive to minimally invasive to open surgical interventions. These technologies may range from molecular to macroscopic scale levels. Overall emphasis is on the engineering of novel image-guided interventions to improve outcomes of interventional procedures. In addition, emphasis includes technologies that expand needed procedural access for individuals otherwise excluded by disease characteristics, co-morbidities, and other parameters. Areas of priority include development of real-time or near real-time novel image-guided technologies, with robust procedural direction or a robust receiver operating characteristic curve. In addition, cost-efficient technologies, appropriate for low resource settings, and/ or applicable to multiple types of interventions are strongly encouraged.
- D. [Magnetic Resonance Imaging](#). Development of in vivo MR imaging and MR spectroscopy, for both animal and human research and potential clinical applications. The emphasis is on the

development of MRI hardware and methodologies, including image acquisition and reconstruction techniques, that would improve the speed, spatial resolution, information content, efficiency, robustness, quality, patient experience, and safety. The emphasis should be on technological development rather than detailed applications to specific diseases or organs.

- E. [Molecular Probes and Imaging Agents](#). Development and biomedical application of molecular probes and imaging agents across all imaging modalities for the visualization, characterization and quantification of normal biological and pathophysiological processes and anatomy in living organisms at the molecular, cellular and organ levels. The emphasis is on engineering of targeting and responsive molecular probes of high sensitivity and specificity for PET and SPECT (radiotracers), MR (T1, T2, CEST, hyperpolarized agents), EPR, CT, optical (fluorescent and bioluminescent probes), ultrasound (microbubbles) and photoacoustic imaging. The imaging agents may be based on nano- and micro-particles, liposomes, dendrimers, proteins, small organic and inorganic molecules etc., and detectable by one or more imaging modalities. Imaging agent development through methodologies such as chemical synthesis, biological mutagenesis, microfabrication, etc., may be pursued with an intent of leading to in vivo biomedical application.
- F. [Nuclear Medicine](#). Research and development of technologies and techniques that create images out of the gamma- ray (SPECT) or positron (PET) emissions from radioactive agents that are injected, inhaled, or ingested into the body. The emphasis is on simulation and development of new detectors, collimators, and readout methods that enhance the signal quality of detecting isotope emissions; designs of novel camera geometries; and correction methods that compensate for the radiation physics properties to improve the clinical reliability of the image. Of interest are improvements and corrections for interaction events in PET detectors and enhancement to time of flight (TOF) image generation methods (reconstructions algorithms); as well as new collimator and camera designs for SPECT.
- G. [Optical Imaging and Spectroscopy](#). Development and application of optical imaging, microscopy, and spectroscopy techniques for improving disease prevention, diagnosis, and treatment in the medical office, at the bedside, or in the operating room. Examples of research areas include fluorescence imaging, bioluminescence imaging, OCT, SHG, IR imaging, diffuse optical tomography, optical microscopy and spectroscopy, confocal microscopy, and multiphoton microscopy. The emphasis is on development of cost effective, portable, safe, and non-invasive or minimally invasive devices, systems, and technologies for early detection, diagnosis, and treatment for a range of diseases and health conditions.
- H. [Ultrasound: Diagnostic and Interventional](#). Development and improvement of technologies for diagnostic or therapeutic uses of ultrasound. The diagnostic ultrasound program includes, but is not limited to the design, development and construction of transducers, transducer arrays, and transducer materials, innovative image acquisition and display methods, innovative signal processing methods and devices, and optoacoustic and thermoacoustic technology. It also includes the development of image-enhancement devices and methods, such as contrast agents, image and data presentation and mapping methods, such as functional imaging and image fusion. The therapeutic ultrasound program includes, but is not limited to the design, development, and construction of transducers, transducer arrays, interventional technologies, adjunct enhancement of non-ultrasound therapy applications, high-intensity focused ultrasound (HIFU), or hyperthermia applications. It also includes non-invasive or minimally invasive interventional surgical or therapy tools, ultrasound contrast agents for therapy, targeted drug delivery, neuromodulation, and biopsy.
- I. [X-ray, Electron, and Ion Beam](#). Research and development of technologies and techniques that create images of internal structures, contrast agents, or molecular probes using x-rays transmitted through the body (CT, mammography) or x-ray stimulation of secondary emissions (x-ray fluorescence tomography). Emphasis is on simulation, design and development of new detector systems; new readout methods that enhance the signal quality for x-ray image generation; designs of novel imaging geometries; algorithms that compensate for the physical properties of the detection system to improve the clinical reliability of the image (reconstruction

algorithms); and approaches to radiation dose reduction, especially in CT. Of interest are diagnostic image enhancements via photon counting, dual energy, and new applications of cone-beam tomography.

- J. [Biomolecular Technologies](#). Development and demonstration of broadly applicable biomolecular technologies to enable new paradigms of human health. The emphasis is on the development of biomolecular technologies and associated computational models for biomedical intervention. NIBIB interests include but are not limited to: molecular switches for synthetic genetic circuits; nucleases and genome editors for DNA manipulation and regulation; engineered viruses and extracellular vesicles for therapeutic agent delivery; transmembrane CARs for extracellular sensing; photoactive molecular complexes for optogenetics.
- K. [Bionics](#). Development and demonstration of broadly applicable bionic systems to enable new paradigms of human health. The emphasis is on the development of bionic systems hardware, software, and methodologies to improve patient health. NIBIB interests include but are not limited to: artificial organs to replace function; electrodes and 3D printed tactile sensors for prosthetics; implantable bioelectronic sensors and actuators for real-time, closed-loop control of tissues and organs.
- L. [Cellular and Multicellular Technologies](#). Development and demonstration of broadly applicable cellular and multicellular technologies to enable new paradigms of human health. The emphasis is on the development of cellular and multicellular technologies and associated computational models for biomedical intervention. NIBIB interests include but are not limited to: synthetic genetic circuits for cellular control and decision-making; engineered bacteria for microbiome regulation; engineered T-cells for immune regulation and cancer therapy; organoids and scaffold-free tissue assemblies for replacing organ function.
- M. [Living Materials](#). Development and demonstration of broadly applicable living materials to enable new paradigms of human health. The emphasis is on the development of living materials and associated computational models for biomedical intervention. NIBIB interests include but are not limited to: bacteria-laden hydrogels to deliver therapeutics; co-designed stem cells and scaffolds to grow implantable tissues.
- N. [Manufacturing and Biomanufacturing Tools](#). Development and demonstration of broadly applicable manufacturing and biomanufacturing tools to enable the translation of new paradigms of human health. The emphasis is on the development of manufacturing and biomanufacturing tools and associated computational models to enable biomedical interventions. NIBIB interests include but are not limited to: bioprinters and bioprinters for 3D tissue construction; continuous production methods for scalable manufacturing of drug delivery vehicles; inline sensors for non-destructive evaluation of manufactured therapeutic cells; bioreactors for organoid manufacturing.
- O. [Medical Devices](#). Development and demonstration of broadly applicable biomedical devices to enable new paradigms of human health. The emphasis is on the development of medical device hardware, software, and models to improve patient health. NIBIB interests include but are not limited to: implantable bioelectronic stimulators and sensors for monitoring and modulating human physiology; wearable sensors for monitoring health vitals; micro devices and injection systems for therapeutic delivery; anti-bacterial and anti-coagulating coatings for implantable devices; biohybrid devices for replacing organ function.
- P. [Medical Simulators](#). Development and demonstration of broadly applicable medical simulators to enable new paradigms of human health. The emphasis is on the development of medical simulator hardware, software, and methodologies, primarily to improve patient outcomes, especially through the reduction of medical errors. NIBIB interests include but are not limited to: virtual coaches incorporating artificial intelligence for performance training in medical procedures and workflows; simulation interfaces to facilitate dissemination and use of virtual environments; realistic representations of anatomy, tissue, instrument, tactile feedback, and collision dynamics; simulator

designs that focus on complicated or rare procedures, including rare adverse events; simulators that replicate realistic workflows, including planning, warm-up exercises, and rehearsal leading up to the actual procedure; portable, easy-to-use simulators for skilled practitioners in rural and low-resource settings.

- Q. [Molecular Materials](#). Development and demonstration of broadly applicable molecular materials to enable new paradigms of human health. The emphasis is on the development of molecular materials and associated computational models for biomedical intervention. NIBIB interests include but are not limited to: lipid nanoparticle coatings for evading the immune system; supramolecular polymers for targeted protein degradation; drug conjugates for targeted drug delivery.
- R. [Nanomaterials](#). Development and demonstration of broadly applicable nanomaterials to enable new paradigms of human health. The emphasis is on the development of nanomaterials and associated computational models for biomedical intervention. NIBIB interests include but are not limited to: magnetic and acoustic nanoparticles for ablating cells and tissues; plasmonic nanorods for tissue suturing; functionalized nanocarriers for drug delivery and immunotherapy.
- S. [Physiomimetic Materials](#). Development and demonstration of broadly applicable physiomimetic materials to enable new paradigms of human health. The emphasis is on the development of physiomimetic materials and associated computational models for biomedical intervention. Projects might focus on: elucidating important engineering design rules or key foundational principles underlying future engineering, including the use of computational methods; prototyping or redesigning platform technologies; characterizing (in vitro, ex vivo, or in vivo) broadly applicable technologies and prototypes. NIBIB interests include but are not limited to: electrically conductive and mechano-sensitive scaffolds for repairing tissue; photoactive adhesives for surgical sealants; biomimetic matrices for T cell activation; artificial cells for therapeutic agent delivery.
- T. [Robotics](#). Development and demonstration of broadly applicable robotic systems to enable new paradigms of human health. The emphasis is on the development of robotic systems hardware, software, and methodologies to improve patient health. NIBIB interests include but are not limited to: robots for minimally invasive surgeries; microgrippers and drills for surgical robots; robotic nurses for isolated patient care; soft robotic exoskeletons to replace lost capabilities; soft elastomeric actuators for assistive robotics.
- U. [Screening and High-Throughput Tools](#). The emphasis is on the development of screening and high-throughput tools and associated computational models to enable biomedical interventions. Projects might focus on: elucidating important engineering design rules or key foundational principles underlying future engineering, including the use of computational methods; prototyping or redesigning platform technologies and approaches; characterizing (in vitro, ex vivo, or in vivo) broadly applicable technologies, prototypes, and lead candidate products. NIBIB interests include but are not limited to: evolution methods for identifying therapeutic protein targets; organs-on-chips for drug screening; microfluidic systems for high-throughput screening of extracellular vesicles.
- V. [Artificial Intelligence, Machine Learning, and Deep Learning](#). Design and development of artificial intelligence, machine learning, and deep learning to enhance analysis of complex medical images and data. The emphasis is on development of transformative machine intelligence-based systems, emerging tools, and modern technologies for diagnosing and recommending treatments for a range of diseases and health conditions. Unsupervised and semi-supervised techniques and methodologies are of particular interest.
- W. [Biomedical Informatics](#). Development of structures and algorithms to improve the collection, annotation, aggregation, anonymization, classification, retrieval, integration, analysis, and dissemination of quantitative and qualitative biomedical data. The emphasis is on using biomedical information to achieve better health outcomes and smarter health care. Examples of technical development areas in this program include but are not limited to informatics tools and resources



such as: databases, standards for enhanced interoperability, collaborative analysis environments, data modeling and representation, and techniques for the integration of heterogeneous data, rational data-driven design of experiments, visualization of data, and digital representation of rich qualitative data. This program is intended to support NIBIB's other program areas in biomedical imaging and bioengineering research.

- X. [Digital Health-Mobile Health and Telehealth](#). Development of enabling technologies that emphasize the integration of wireless technologies with human and biological interfaces. This program includes the development of software and hardware for telehealth and mobile health studies. This program includes the development of software and hardware for telehealth and mobile health studies and the input and delivery of healthcare information digitally for the analysis or monitoring of health or disease status. The emphasis is on developing mobile health technologies driven by clinical needs and integrating these technologies in healthcare delivery, wellness, and daily living.
- Y. [Point of Care Technologies-Diagnostics](#). Development of rapid in-vitro diagnostic technologies and monitoring platforms that provide real time medical evaluation and analysis of the disease status or condition at the time and place of patient care. The program includes the delivery of healthcare that is safe, effective, timely, patient-centered, efficient, and available in centralized and decentralized locations. The emphasis is on developing technologies driven by clinical needs. Examples of technology development areas in this program include but are not limited to disposable lateral flow assays, nucleic acid testing platforms, glucose monitoring devices, etc.
- Z. [Image Processing, Visual Perception, and Display](#). Design and development of algorithms for post-acquisition image processing and analysis, the development of theoretical models and analysis tools to evaluate and improve the perception of medical images, and the development of visualization tools for improved detection. The emphasis is on using image data to achieve better health outcomes and smarter health care. Examples of technology development areas in this program include but are not limited to models, algorithms, software, methodologies, and other tools that will: facilitate medical imaging research; support clinical detection, diagnosis and therapy; and improve patient healthcare.

### **Contact Information**

#### **For additional information on research topics, contact:**

Dr. Kari Ashmont  
National Institute of Biomedical Imaging and Bioengineering  
Telephone: 301-451-4772, Fax: 301-480-1614  
Email: [NIBIB-SBIR@mail.nih.gov](mailto:NIBIB-SBIR@mail.nih.gov)

#### **For administrative and business management questions, contact:**

Mr. James Huff  
National Institute of Biomedical Imaging and Bioengineering  
Telephone: 301-451-4786, Fax: 301-451-5735  
Email: [huffj@mail.nih.gov](mailto:huffj@mail.nih.gov)

## NATIONAL CANCER INSTITUTE (NCI)

### Mission

The National Cancer Institute's SBIR Development Center program is one of the nation's largest sources of financing for small businesses engaged in technology innovation. NCI's funding, mentoring, and networking assistance is offered to small businesses demonstrating promising next-generation cancer cure technologies, with the ultimate goal being successful commercialization and benefiting public health. NCI's SBIR/STTR Programs offer funding for therapeutic agents and devices; *in vitro* and *in vivo* diagnostics, including companion diagnostics and imaging agents; agents and technologies for cancer prevention; tools for research in cancer biology, cancer control, and epidemiology; digital health, including health information technology and bioinformatics; and many more areas of interest to the NCI.

The goal of NCI's SBIR/STTR program is to increase small business participation and private-sector commercialization of novel technologies that can prevent, diagnose, and treat cancer. The major NCI SBIR/STTR portfolio areas are listed below as a guide to general technology areas funded through the program. However, NCI will accept any applications outside these topic areas, and proposing innovative cancer-related technologies with strong commercial potential is encouraged.

### Budget Guidance

For budgetary, administrative, or programmatic reasons, NCI may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). However, for certain research topics, the U.S. Small Business Administration has approved a list of [SBA-Approved Waiver Topics](#) for which the NCI generally will fund Phase I applications with higher budgets up to \$400,000 total costs combined over all years, and project periods up to 2 years; similarly, for certain research topics, NCI will consider Phase II applications with higher budgets up to \$2,250,000 total costs combined over all years, and project periods up to 3 years.

### Specific SBIR and STTR Program Information

NCI SBIR program is technology agnostic. We welcome all innovative solutions with commercial potential that is relevant to the mission of the NCI and that reduces the burden on cancer patients, their caregivers, and providers.

For up-to-date information on high-priority technology areas, and to learn about programmatic initiatives and upcoming events, visit the NCI SBIR Development Center homepage: <http://sbir.cancer.gov>.

In addition, please see the contact list at the end of the NCI section to identify the NCI SBIR/STTR Program Director(s) that specializes in your technology area.

**NCI will accept applications for support of clinical trials in the NCI priority area mentioned above or any other areas that are relevant to the NCI's mission.**

### Prior to Submission

Applicants are strongly encouraged to contact SBIR/STTR staff prior to submitting any

application. To schedule a meeting, please email [ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov) with a copy of your specific aims page that includes answers to the following questions:

- What is your product?
- What would be the impact of your technology on cancer patients, providers, or caregivers?
- How is your product innovative and how is it different from the current standard?
- What are your aims for the application? What will be your milestones or success criteria?
- Who is the end-user of your product? Who is the purchaser?

For NCI-related SBIR Information, visit <http://sbir.cancer.gov>.

## **Specific Funding Opportunities and Programs**

### **1. Commercialization Readiness Pilot (CRP) and Phase IIB Competing Renewal**

#### **Awards CRP**

The National Cancer Institute (NCI) welcomes CRP applications from companies that have active or completed NCI SBIR (Phase II and Phase IIB) or STTR (Phase II) awards ([PAR-20-128](#)). Please note that NCI will provide funding support up to a maximum of \$250,000 in total costs (direct costs, indirect costs, and fee). Potential applicants are strongly encouraged to contact NCI SBIR Program staff to discuss prior to submission the CRP activities for which support will be requested. The NCI may decline funding of any application for reasons of program balance or budget. NCI does not participate in the SBIR/STTR Commercialization Readiness Pilot Program Technical Assistance and Late-Stage Development (SB1) NOFOs (PAR-20-129 or PAR-20-130). For SBIR/STTR Phase II awardees in need of additional assistance for late-stage development and/or clinical trials, the NCI recommends its SBIR Phase IIB program.

#### **Phase IIB**

The NCI does not accept applications for Phase IIB SBIR competing renewal awards through this Omnibus solicitation. However, the NCI offers Phase IIB opportunities in the form of the NCI SBIR Phase IIB Bridge Award, which is announced via a separate funding solicitation: <https://sbir.cancer.gov/bridge>. Please note that NCI will provide funding support up to a maximum of \$4,500,000 in total costs (direct costs, indirect costs, and fee). The NCI Phase IIB Bridge Award is designed to support the next stage of development for cancer-related technologies previously funded under SBIR or STTR Phase II awards from any Federal agency. The purpose of this award is to address the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization. To achieve this goal, the Bridge Award funding opportunity is specifically designed to incentivize partnerships between federally funded SBIR Phase II awardees and third-party investors and/or strategic partners. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds).

To ensure that you will be notified upon the release of the NCI SBIR Phase IIB Bridge Award solicitation, please sign up for the NCI SBIR mailing list: <https://bit.ly/NciSbirEmailSignUp>. If you have any questions regarding the NCI SBIR Phase IIB Bridge Award, please contact your Phase II program director.

## 2. Technical and Business Assistance (TAB A) Funding

NCI will consider well-justified Technical and Business Assistance (TAB A) costs up to the limits specified on the [NIH SEED Website](#). These costs can be requested in addition to the Phase I and II budget caps set by NCI. TAB A costs must be requested under the original application. NCI will not fund TAB A costs as a supplement and does not participate in the administrative supplement program for TAB A ([NOT-OD-21-062](#)).

### Clinical Trials

Applicants are strongly encouraged to contact SBIR/STTR staff prior to submitting any application containing clinical trials.

Does NCI accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NCI accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	<a href="https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities">https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities</a>
Does NCI support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	R21, R01, P01, K08 <a href="https://www.cancer.gov/grants-training/grants-funding/funding-opportunities">https://www.cancer.gov/grants-training/grants-funding/funding-opportunities</a>

### Research Topics

NCI will accept applications in any of the NCI priority areas mentioned below or any other areas that are relevant to NCI's mission. NCI is technology agnostic and will fund any technology as long as it benefits cancer patients, providers, or caregivers. Applications proposing innovative cancer-related technologies, with strong commercial potential, that fall outside these topic areas are also welcomed through the Omnibus Solicitation. NCI accepts and encourages SBIR & STTR applications to support clinical trials.

#### **Major NCI SBIR/STTR Portfolio Areas:**

- Therapeutics (e.g., Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)
- *In Vitro* and *In Vivo* Diagnostics (e.g., Companion Diagnostics and Prognostic Technologies)
- Imaging Technologies (e.g., Agents, Devices, and Image-Guided Interventions)
- Devices for Cancer Therapy (e.g., Interventional Devices, Surgical, and Radiation and Ablative Therapies, Hospital Devices)
- Agents and Technologies for Cancer Prevention
- Technologies for Cancer Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Cancer Research)
- Tools for Cancer Biology Research
- Digital Health Tools and Software Platforms for Cancer-Related Technologies

### Diversity Statement from NCI SBIR

The statutory purpose of the SBIR program is to strengthen the role of innovative SBCs in Federally

funded research or research and development (R/R&D) ([See the Policy Directive](#)). Specific program purposes are to: (1) stimulate technological innovation; (2) use small business to meet Federal R/R&D needs; (3) foster and encourage participation by socially and economically disadvantaged SBCs (SDBs), and by women-owned SBCs (WOSBs), in technological innovation; and (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity, and economic growth. To understand more about how the NCI SBIR/STTR program fosters and encourages participation by WOSBs and SDBs, please check the following link: <https://sbir.cancer.gov/diversity>

### **Contact Information**

**For additional information about the NCI SBIR/STTR programs, please contact the NCI SBIR Development Center:**

National Cancer Institute  
Small Business Innovation Research (SBIR) Development Center  
9609 Medical Center Drive  
Rockville, MD 20850  
Website: <http://sbir.cancer.gov>  
Email: [NCIsbir@mail.nih.gov](mailto:NCIsbir@mail.nih.gov)  
Phone: 240-276-5300

**For additional information on research topics, please contact a Program Officer with the relevant area of expertise:**

Michael Weingarten, MA  
Director, NCI SBIR Development Center  
Email: [weingartenm@mail.nih.gov](mailto:weingartenm@mail.nih.gov)

Gregory Evans, PhD  
Program Director and Team Leader  
Email: [evansgl@mail.nih.gov](mailto:evansgl@mail.nih.gov)  
*Areas of Expertise: Therapeutics (Immunotherapy, Gene Therapy), Cancer Imaging, Cancer Control, Tools for Cancer Biology Research, and Digital Health*

Jonathan Franca-Koh PhD, MBA  
Program Director and Team Leader  
Email: [jonathan.franca-koh@nih.gov](mailto:jonathan.franca-koh@nih.gov)  
*Areas of Expertise: Cancer Biology, Biologics, Small Molecules, and Cell-Based Therapies*

Monique Pond, PhD  
Program Director and Team Leader  
Email: [monique.pond@nih.gov](mailto:monique.pond@nih.gov)  
*Areas of Expertise: Biologics, Small Molecules, Therapeutic Devices, Digital Health, Regulatory Resources*

Patricia Weber, DrPH  
Program Director  
Email: [weberpa@mail.nih.gov](mailto:weberpa@mail.nih.gov)  
*Areas of Expertise: Digital Health and Therapeutics (Small Molecules, Biologics, Immunotherapy)*

Xing-Jian Lou, PhD  
Program Director  
Email: [loux@mail.nih.gov](mailto:loux@mail.nih.gov)  
*Areas of Expertise: In Vitro Diagnostics and Therapeutics (Gene Therapy, Biologics, Small Molecules)*

Ming Zhao, PhD  
Program Director  
Email: [zhaoming3@mail.nih.gov](mailto:zhaoming3@mail.nih.gov)  
*Areas of Expertise: In Vitro Diagnostics, Cancer Stem Cells, Molecular Imaging, Bioinformatics, Therapeutics (Small Molecules, Biologics, Immunotherapy), and Cancer Control (Community-Based Participatory Research)*

William Bozza, PhD  
Program Director  
Email: [william.bozza@nih.gov](mailto:william.bozza@nih.gov)  
*Areas of Expertise: Biologics, Protein Therapeutics, Regulatory (CMC)*

Sarra Djemil, PhD  
Program Director  
Email: [sarra.djemil@nih.gov](mailto:sarra.djemil@nih.gov)  
*Areas of Expertise: Therapeutics, Digital Health, Mentoring*

Saroj Regmi, PhD  
Program Director  
Email: [saroj.regmi@nih.gov](mailto:saroj.regmi@nih.gov)  
*Areas of Expertise: Therapeutics, Diagnostics, Imaging, Digital Health, Investor Initiatives, Small Business Transition Grant, I-Corps*

Swamy Tripurani, PhD  
Program Director  
Email: [swamy.tripurani@nih.gov](mailto:swamy.tripurani@nih.gov)  
*Areas of Expertise: Therapeutics, Biologics, Small Molecules, Diagnostics, Devices, and Regulatory (CMC and Nonclinical)*

Melissa Li, PhD  
Program Director  
Email: [melissa.li@nih.gov](mailto:melissa.li@nih.gov)  
*Areas of Expertise: Biologics, Small Molecules, Digital Health*

Linda Zane, PhD  
Program Director  
Email: [linda.zane@nih.gov](mailto:linda.zane@nih.gov)  
*Areas of Expertise: Therapeutics, Diagnostics, Research Tools*

# **EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)**

## **Mission**

The mission of the NICHD is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

The NICHD has a broad and diverse research portfolio, including biological, behavioral, and clinical research related to conception and pregnancy, normal and abnormal development in childhood, reproductive health, rehabilitation, and population dynamics across the lifespan.

For up-to-date information on priority research areas of scientific interest to the NICHD, please visit our home page at <http://www.nichd.nih.gov>.

## **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). It is strongly encouraged to contact program staff prior to applying.

The NICHD received a budgetary guideline waiver from the Small Business Administration for applications relating to a limited list of scientific topics in [SBA-Approved Waiver Topics](#). For these the NICHD will accept applications up to \$400K total costs for Phase I and \$2.25M for Phase II. Applicants should propose a budget that is reasonable and appropriate for completion of the research project and requests for these budget levels must be very well justified. Applicants are encouraged to contact the listed NICHD Branch Contact Program Officer for scientific-related questions about a project's eligibility for a budgetary waiver.

For general budgetary questions, applicants should contact NICHD's SBIR/STTR Grants Management Coordinator. **The NICHD may decrease the budget or length of an award or decide not to fund an application for budgetary, administrative, or programmatic reasons.**

## **Specific SBIR and STTR Program Information**

The NICHD will generally consider clinical trial proposals consistent with the topics listed below with the following exception:

### **Developmental Biology and Congenital Anomalies Branch**

The [DBCAB](#) does not support clinical trials through the SBIR/STTR program.

## **Pre-submission Resources & Commercialization Assistance**

There are several resources and programs available throughout the SBIR/STTR process. For more information, please visit our [Commercialization Resources webpage](#).

## **Specific Funding Opportunities and Programs**

In addition to the Omnibus program announcement, for up-to-date NICHD releases on targeted **funding announcements and programmatic initiatives** visit: <https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities> or [https://www.nichd.nih.gov/grants-funding/SBIR\\_STTR/Pages/default.aspx](https://www.nichd.nih.gov/grants-funding/SBIR_STTR/Pages/default.aspx).

## **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

The NICHD accepts Phase IIB SBIR Competing Renewal applications to support additional R&D necessary for approval of a federal regulatory agency (e.g., FDA, FCC). Such products may include medical implants, pediatric devices, drugs, vaccines, and new treatment or diagnostic tools

Applicants who received NICHD SBIR Phase II support and who are currently Phase II awardees are eligible. If the project meets the criteria for a budgetary waiver (see [SBA-Approved Waiver Topics](#)), the Phase IIB should not exceed \$3M total costs for three years. The amount of award may vary year to year depending on the research proposed. **Funding priority will be given to those small business concerns that show the ability to develop innovative products and demonstrate growth towards independence from the SBIR/STTR programs.**

**Prospective applicants are strongly encouraged to contact NICHD program staff well in advance of submitting a Phase IIB Competing Renewal application.**

### **Clinical Trials**

Does NICHD accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NICHD accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	RFAs <a href="https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities">https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities</a>
Does NICHD support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	Check the NICHD website for active NOFOs: <a href="https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/active-foa/Pages/default.aspx">https://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/active-foa/Pages/default.aspx</a>

### **Research Topics**

The major NICHD research priority areas for each Branch are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of the NICHD are also considered through this Omnibus solicitation.

#### **A. Child Development and Behavior Branch**

The CDBB encourages innovative developmentally-sensitive, theoretically-grounded, and evidence-based small business initiatives that develop technology and products addressing the psychological, social and emotional, psychobiological, language, numerical, literacy, cognitive and intellectual development and health of persons from infancy through the transition to adulthood, recognizing the important role others have in contributing to the healthy development of an individual. Products that target at-risk populations and/or exploit new technologies that can expand the effective reach or inclusion of underserved populations in order to encourage healthy development and/or our understanding of the influences of context and/or behavior on development are especially encouraged. CDBB is also interested in research on innovative approaches to both imaging and other non-invasive measurement approaches to capture real time brain activation activity in typical and atypical infants and young children (birth to age three).

Foci of specific interest include, but are not limited to (please also see the [CDBB description for research priorities](#)):

- **Enhancing Bilingual and Biliteracy Development:** Adaptive learning technology to enhance bilingual and/or biliteracy development in English-language learning children and youth.



- **Bi- or Multi-Lingual Measures of Neurodevelopment:** Develop easy to administer objective neurodevelopmental measures from evidence-based neurocognitive research specific to typically developing infants through pre-K children from diverse language homes that are shown to correlate with development of brain connectivity and activation. Remote administration measures are a high priority.
- **Pediatric Primary Care Behavioral and Health Promotion Interventions:** Facilitate research on the impact of behavioral and health promotion interventions in pediatric primary care and related clinical settings with a focus on child and adolescent health outcomes.
- **Psychosocial Adjustment for Individuals in High-Risk Environments:** Develop measures to identify and tools to stimulate developmental factors and mechanisms which promote short- and long-term psychosocial adjustment for children and adolescents exposed to high-risk family and neighborhood environments.
- **School Readiness Skills in Economically and Socially Disadvantaged Children:** Develop mobile device apps and/or hand-held devices that assess and/or promote the development of executive functioning (EF) and school readiness skills and abilities in infancy and early childhood and in diverse populations of children as well as measures of home, childcare and preschool environments and practices that are related to child learning and development.
- **Reading, Writing, and Mathematics Struggling Learners:** Develop assistive technology to enhance learner outcomes for individuals that struggle to acquire literacy and/or numeracy skills, grounded in current scientific understanding of these challenges.
- **Assessment and Enhancement of Reasoning Development:** Develop validated and specific assessment tools that are sensitive to contributing factors (e.g., biobehavioral, environmental, cultural, academic, and cognitive factors) to facilitate research on and the promotion of neurocognitive development of reasoning (e.g., quantitative, deductive, inductive, causal) in typically developing populations.
- **Fostering inclusion of typically-developing or at-risk infants, toddlers and children in neuroimaging activities:** Develop products or new strategies to facilitate neuroimaging of typically-developing or at-risk infants, toddlers and children.

## B. Contraception Research Branch

The [CRB](#) supports research on developing new and improved methods of fertility regulation as well as research on the benefits and risks of contraceptive drugs, devices and surgical procedures.

Areas of interest include, but are not limited to:

- Development of new and improved methods of fertility regulation, for men and women, that are safe, effective, inexpensive, reversible and acceptable with priority given to non-hormonal and on-demand methods
- Synthesis and testing of novel chemical compounds that are potential contraceptives
- Multipurpose prevention technologies designed to prevent sexually transmitted infections, such as HIV, as well as pregnancy

## C. Developmental Biology and Congenital Anomalies Branch

The [DBCAB](#) supports biomedical research on the cellular, molecular, and genetic aspects of typical and atypical embryonic development including early embryogenesis, organogenesis, as well as topics in stem cell and regenerative biology. The overall goal is to promote research on developmental biology to understand the causes of structural birth defects.

Areas of interest include but are not limited to:

- Development of new model systems (animal or other) to study developmental mechanisms and causes of structural birth defects
- Innovative technologies for *in vivo* imaging of developmental processes (cell and tissue dynamics) and gene expression
- Development of antibodies, novel ligands, and other probes to facilitate our understanding of typical and atypical embryonic development in model organisms
- Technologies for quantitative measurement of physical properties of cells/tissues *in vivo* during development
- Innovative technologies for studying metabolomics in developing vertebrate embryos
- Technologies to facilitate and advance systems biology approaches to the study of embryonic development and structural birth defects
- Technologies to facilitate and advance high throughput chemical screening (including small molecules) for advancing structural birth defects research
- Software development to facilitate the collection and analyses of data generated using medium-high throughput screening platforms in model systems (model organisms, cell-based models)
- Software development to facilitate the collection, mining and analyses of genomic and phenotypic data from children affected with structural birth defects, and cross-analysis with model organism data
- Development of user-friendly software for biomedical researchers with limited knowledge of computational biology to analyze large-scale human and other datasets associated with structural birth defects
- Technologies/methodologies to generate, and software to mine, data related to wound healing and regenerative responses across animal species
- Novel reagents for activation and mobilization of endogenous/adult stem cells to promote *in vivo* tissue regeneration
- Methodologies to drive limb regeneration in higher vertebrates (including in mammals) that might otherwise lack the capacity for regeneration.
- Technologies for iPSC-based regenerative medicine in the context of structural birth defect
- Screening technologies for small molecules in human Embryonic Stem (ES) Cells or Induced Pluripotent Stem Cells (iPSCs) and disease specific iPSCs for targeted modification of regulatory networks affected in structural birth defects

#### D. Fertility and Infertility Branch

The [FIB](#) supports research on the reproductive processes of men and women and of animals with similar reproductive systems related to developing safer and more effective means of regulating, preserving or achieving fertility.

Areas of interest include but are not limited to:

- Development of reagents and tools, such as high-resolution technologies to facilitate study of reproductive and developmental processes, including gamete and early embryo development, and reproductive track development
- Development of techniques and identification of novel biomarkers to produce, identify, and use healthy gametes as well as advancement on preservation of human gametes
- Development of organoid cultures and physiomimetic systems ideal for study of gametogenesis and normal or diseased reproductive tissues/organs
- Development of improved methods of growing and differentiating stem cell lines *in vitro*, including feeder cell-free approaches to facilitate reproductive research
- Development of improved technologies for the reprogramming of cells, including embryonic stem cells or adult cells, into eggs and sperm
- Development of improved technologies for preimplantation genetic diagnosis
- Development of omics technologies to diagnose impairments in sperm function, fertilization, ovulation, implantation, decidualization and other aspects of reproductive processes

- Use of genomics and proteomics to develop novel diagnostics and treatments for reproductive diseases and disorders
- Use of semen, vaginal or cervical fluid, or menstrual effluent to diagnose fertility status or other health conditions
- Development of novel assays, kits, and devices to monitor and treat infertility
- Development of Artificial Intelligence techniques/methods for selection of best sperm cells, oocytes, and embryos to generate better predictive models for in vitro fertilization
- Development of innovative technologies for point-of-care testing for fertility/infertility and reproductive diseases and disorders
- Development of patient-specific treatment regimen for infertility diseases using Artificial Intelligence methods/technologies
- Development of tools, technologies or apps for diagnosis and treatment of infertility in resource limited settings to increase community and individual resources to address infertility
- Development of tissue engineering technologies for uterine tissue regeneration and reproductive track reconstruction for treatment of infertility
- Identification and/or validation of putative male or female infertility targets
- Development of novel drugs or devices to treat male or female infertility.
- Development of high-throughput screening methodologies for small molecule drugs addressing infertility

#### **E. Gynecologic Health and Disease Branch**

The [GHDB](#) supports biomedical research related to gynecologic health throughout the reproductive lifespan, beginning at puberty and extending through perimenopause.

Areas of interest include, but are not limited to:

- Development of new diagnostic approaches and treatments for female pelvic floor disorders, including drugs, and devices used for treatment of pelvic organ prolapse, urinary incontinence, fecal incontinence, and other female pelvic floor disorders
- Development of new diagnostic methods and novel surgical and non-surgical treatments for uterine fibroids, endometriosis, adenomyosis, and benign ovarian cysts. Non-invasive diagnostics and/or diagnostics that make use of menstrual effluent are of particular interest.
- Production of marketable novel or improved methods, devices, and technologies for the diagnosis, monitoring and therapy of gynecologic pain disorders including chronic pelvic pain, vulvodynia/ vestibulodynia, and dysmenorrhea
- Generation of new approaches for the diagnosis, monitoring and treatment of abnormal menstrual cyclicity
- Surgical and non-surgical treatments for girls and women with reproductive tract abnormalities, including congenital structural abnormalities and complications from female genital cutting
- Devices and/or technologies designed to address surgical challenges in gynecologic surgeries, including hysterectomy
- Technologies designed to apply -omics platforms (genomics, proteomics, metabolomics etc.) to questions of gynecologic health and disease

#### **F. Intellectual and Developmental Disabilities Branch**

The [IDDB](#) sponsors research aimed at preventing, diagnosing, and ameliorating intellectual and developmental disabilities (IDD). Emphasis is on studies related to IDD, including common and rare neurodevelopmental and neuromuscular disorders, such as autism spectrum disorders, Down, Fragile X, and Rett syndromes, mitochondrial conditions, inborn errors of metabolism, and others.

Areas of interest include, but are not limited to:

- Innovative tools, including molecular, imaging, statistical or behavioral tools, to characterize the etiology and pathophysiology of abnormal nervous system development.
- Methods and devices to delineate genetic, genomic, and epigenetic causes of IDD and develop gene-based treatments.
- Methods or devices designed to screen for, diagnose, treat, and manage IDD and other conditions, particularly those identified or identifiable by newborn screening.
- Assessment tools for use in the clinic or community settings to enable the accurate measurement of change in response to interventions.
- Development of early interventions leading toward the prevention, diagnosis, treatment, and management of IDD.
- Methods or devices to develop or adapt smart technologies (such as wearable devices, mobile health applications (apps), and electronic medical records (EMR)-based tools) to assist in remote health monitoring, to service as point-of-care diagnostic tools, and/or to enhance screening, diagnosis, prevention, treatment, or management for individuals with IDD to improve their quality of life.
- Development of assessment measures or treatments for co-morbid symptoms in those with IDD including disordered sleep, self-injurious behaviors, obesity, gastrointestinal dysfunction, seizures/epilepsy, attention deficit/hyperactivity disorder, anxiety, depression, psychosis, immune dysregulation, self-injurious behaviors, and ADHD and other mental health disorders.
- Innovative and new digital technologies and mHealth solutions for improving transition of adolescents to adult healthcare providers by improving health literacy, enabling self-management, and encouraging adherence to existing treatments among adolescents.
- Methods and devices to facilitate inclusion of people with all levels of IDD in research and clinical care – both research/care targeted toward IDD populations and research/care for more general populations where people with IDD are typically categorically excluded.

#### **G. Maternal and Pediatric Infection Disease Branch**

[MPIDB](#) supports domestic and international research on human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) and other infectious diseases (such as CMV, Syphilis, tuberculosis, hepatitis and malaria) in people of child bearing age, pregnant people, mothers, fetuses, infants, children and adolescents. Specific areas of interest include but are not limited to epidemiology, clinical manifestations, immune-pathology, pathogenesis, transmission, treatment and prevention (including immune-therapeutics like monoclonal antibodies, vaccines and other biomedical modalities) of HIV infection, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, and other pertinent infectious diseases in children, adolescents and pregnant people, with a focus on prevention of vertical transmission of HIV and other congenital infections, and HIV-related and other infectious-disease related complications in these populations.

Additional areas of interest include:

- New technologies relevant to resource-limited countries for:
  - Screening, diagnosis, and management of infectious diseases in pregnant women, infants, and children, including but not limited to HIV such as SARS-CoV-2, congenital CMV, congenital Syphilis, tuberculosis, and Zika virus)
  - Rapid assays to monitor disease activity and response to therapy as well as immune response to vaccinations against relevant infections in infants and children (e.g., malaria, tuberculosis), which can be used at the individual level and/or as part of public health campaigns (e.g., eradication of outbreaks and prevention of spread)
  - Diagnosis and treatment of HIV-related co-morbidities (e.g., diagnosis of tuberculosis, STIs)
  - Diagnosis and treatment of SARS-CoV-2 infection-related outcomes in mothers and infants

- Simple and less technologically demanding point of care assays to monitor CD4 cell percentage/count, HIV viral load, or other surrogate markers of HIV disease progression in children
- Simple and easy to use/at home use diagnostics and point of care assays to monitor clinical symptomatology and prognosis of SARS-CoV-2 infection and recovery in children
- Interventions designed to promote or optimize medication adherence
- Child-friendly formulations (preferably not liquid preparations) of drugs used to treat or prevent HIV infection, complications of HIV infection, and/or other high-priority infections such as tuberculosis, hepatitis, Syphilis, CMV, and malaria relevant to children, particularly in resource-limited countries; Fixed-dose drug formulations and innovative methodologies for development of solid heat stable formulations capable of being administered to young children (e.g., sustained release beads, etc.) and/or improve pill or volume burden
- Innovative long-lasting drug formulations for antiretroviral and other anti-infective drugs that would allow less frequent drug administration (e.g., once daily, weekly, or monthly)
- Simple, standardized, validated tools to evaluate neurodevelopmental outcomes in children
- Innovative data collection and database development approaches to leverage and link electronic medical records and/or other health information systems to better understand treatment and prevention of infectious diseases among infants, children, adolescents, and people of child-bearing age.
- Biomedical modalities including vaccines and methods to assess efficacy of vaccines, to prevent acquisition of HIV and other infectious diseases in children, adolescents, and women.
- Topical microbicide agents, wearable, implantable, or insertable devices releasing medications alone or as part of multipurpose prevention technologies (MPTs), to prevent sexual acquisition of HIV and other sexually transmitted infections in adolescents, adult women, and pregnant or postpartum people.
- New, non-invasive technologies to evaluate complications of antiretroviral drugs (e.g., mitochondrial toxicity, bone toxicity) in HIV-infected infants, children, adolescents, pregnant people, and their fetuses.
- New or improvements to existing technologies for measuring the HIV latent reservoir, or other long-term effects of infectious diseases, including high-throughput, visualization algorithms, and improvement in assay reliability and sensitivity in children.

## H. Obstetric and Pediatric Pharmacology and Therapeutics Branch

The [OPPTB](#) supports research and research training on the development and use of safe and effective therapeutic drugs and therapeutic-related medical devices for children and pregnant and lactating people, including during the postpartum period. The branch promotes basic, translational, and clinical research to improve the safety and efficacy of therapeutics, primarily pharmaceutical drugs and medical devices. It is responsible for developing and supporting a comprehensive national effort to increase the knowledge base for understanding how to appropriately treat disease during pregnancy, lactation, infancy, childhood, and adolescence using evidence-based therapeutic approaches. This includes support for the development and validation devices to inform treatment decisions and enhance precision drug delivery. The goal of these efforts is to assure that medications are appropriately tested for dosing, safety, and effectiveness for individuals within their target populations. Of note: NICHD considers applications for pediatric conditions that have significant efforts at other NIH institutes (e.g., sickle cell disease, pediatric oncology, juvenile diabetes) to be of lower programmatic priority.

Applications to advance the study of obstetric and pediatric therapeutics include but are not limited to:

- Understanding Differences and Heterogeneity in Pediatric Disease Treatment. Research to quantitatively understand differences in drug action and related pathophysiology between childhood and adult disease and conditions unique to pediatrics. This includes developing tools (e.g., biomarkers, outcome measures, and physiologically based pharmacokinetic/pharmacodynamic models) to support pediatric drug discovery and

- development and to facilitate the application of precision medicine approaches in children.
- **Pharmacology and Pathophysiology of Pregnancy.** Developmental pharmacology research and approaches that explore the intersections of physiological changes in pregnant people and during fetal development with drug action (e.g., pharmacokinetic, pharmacodynamics, and pharmacogenomics) and with molecular pathways that may serve as novel therapeutic targets for disease-modifying therapies specific to these populations. Critical areas include pain management in pregnant and lactating people and treatment of gestational diabetes, preeclampsia, and prevention of preterm delivery.
- **Novel Alternatives to Traditional Pediatric and Obstetric Clinical Trials.** Development of innovative approaches and algorithms to determine drug dosing, safety, and effectiveness in children and in women during pregnancy and lactation. This includes artificial intelligence-driven modeling and simulation methods, novel approaches to utilizing existing data and archived biosamples/biospecimens, and pragmatic trials.
- **Population- and Individual-Specific Diagnostic and Therapeutic Devices** that can advance precision medicine through individualized diagnosis, drug delivery, and non-drug therapy appropriate for use in neonates, children, and obstetric and lactating people. This may include 3D bioprinting, AI-enhanced pharmacometrics modeling, AI-driven diagnostic and decision-making tools, novel drug delivery devices, and formulations.
- **New Uses for Drugs, Biologics, and Other Therapeutics.** This includes the development and use of preclinical experimental models (e.g., animal models and human biomimetics), use of organotypic microphysiologic cell culture systems and strategies for assessing pharmacologic and toxicologic effects of therapeutics, use of genetically diverse model organisms to assess precision prescribing approaches for interindividual manifestation of disease or response to therapeutic agents, and computation models or the accumulation of real-world evidence in support of new therapeutic uses.

## I. **Pediatric Growth and Nutrition Branch**

The [PGNB](#) supports research designed to support short and long-term health so that children can achieve their full potential through an expanded understanding of those factors that influence metabolism, growth (body composition and linear growth) and neurodevelopment. An additional focus is on those biological (e.g., genetic, nutritional, endocrinological) factors that contribute the early life origins of non-communicable disease (e.g., obesity, diabetes, cardiovascular disease, osteoporosis). The PGNB encourages research that focuses on detecting the biological antecedents of these conditions during pregnancy, infancy, and childhood.

Areas of interest include, but are not limited to:

New research tools, improved measurement methods, and technologies that enhance our understanding of:

- **Growth:**
  - Physical growth, body composition, bone health, nutrition, and obesity
  - Determinants of normal bone mineral accretion and peak bone mass. Interactions of muscle and bone during infancy and childhood
  - Neuroendocrinology of puberty, linear growth, body composition
  - Mechanisms of hormone action during linear growth, pubertal maturation, and other aspects of physical development
- **Biological antecedents of childhood obesity and its short and long-term consequences:**
  - Genetic and molecular mechanisms of obesity, psychosocial risks of obesity, and therapeutic interventions for obesity in children and adolescents
  - Impact of early life exposures including infant feeding practices on short and long-term health and development
- **Biology of nutrition as it pertains to health and development (physical and neurological function) during pregnancy, infancy and childhood including discovery, development and deployment of biomarkers for early detection of:**
  - Mal-(over-/under) nutrition; including biomarkers of exposure, status, function and effect (i.e.,

- impact on early life development including neurodevelopment)
- Enhanced understanding of the role of human milk in child health and development.
- Maternal nutrition (pre-pregnancy, pregnancy, and lactation)
- Novel approaches to enhanced infant feeding practices in term and pre-term infants
- Developmental origins of health and disease including:
  - Ascertain biomarkers early in life that predict the onset of chronic diseases such as diabetes, osteoporosis, and the metabolic syndrome later in life. The PGNB emphasizes the life course model to develop primary preventive approaches to chronic diseases.
  - Develop platforms for implementation of biomarkers of disease status, nutritional status, and biological function from infancy through adolescence

## J. Pediatric Trauma and Critical Illness Branch

The [PTCIB](#) supports research and research training in pediatric trauma, injury prevention, and critical illness across the continuum of care. These efforts include research focused on the prevention, treatment, and management of physical and psychological trauma and the surgical, medical, psychosocial, and systems interventions needed to improve outcomes for critically ill and injured children and adolescents.

Additionally, the PTCIB supports basic, clinical, and translational research that explores short- and long- term consequences of traumatic experiences such as exposure to disasters, all forms of violence against children, exposure to critical illness environment, and experiences of bereavement, grief, and loss.

Applications of interest include, but are not limited to the research and development of:

- Technologies, devices, and equipment used by pediatric critical care, emergency care, and trauma care personnel.
- Novel technologies in caring for injured children prior to and during transport to treatment settings.
- Tools and technologies for screening and diagnosis of injuries related to forms of child maltreatment.
- Devices and innovative therapeutic technologies for management of medical conditions and related problems stemming from critical illness and serious or life-threatening injuries.
- Preventive intervention tools, materials, and technologies designed to improve clinical practice, parenting, and social system support for injured or traumatized children.
- Tools, materials, and technologies designed to reduce pediatric trauma exposure and the number and severity of pediatric injuries and deaths.
- Tools and technologies to improve the environment of pediatric intensive care including resources to promote patient safety and to enhance clinical education and training of critical care personnel
- Tools and technologies that support the diagnoses and treatment of critical illness in children, including nosocomial infections and iatrogenic injury.

## K. Population Dynamics Branch

[PDB](#) supports research and research training in demography, reproductive health, and population health. In **demography**, the Branch supports research on the scientific study of human populations, including fertility, mortality and morbidity, migration, population distribution, nuptiality, family demography, population growth and decline, and the causes and consequences of demographic change. In **reproductive health**, the Branch supports behavioral and social science research on

sexually transmitted diseases, HIV/AIDS, family planning, and infertility. In **population health**, the Branch supports data collection and research on human health, productivity, behavior, and development at the population level, using such methods as inferential statistics, natural experiments, policy experiments, statistical modeling, and gene/environment interaction studies.

Applications are encouraged, but are not limited to these areas:

- Technological innovations or inventions to improve collection of biomarker and anthropometric data in large population-representative surveys
- Hardware or software to improve the collection of accurate cause of death information or health diagnosis such as information related to infant and maternal morbidity and mortality, in large population-representative surveys or in administrative data sets
- Methods for integrating data science, including artificial intelligence and machine learning, into demographic research
- Methods for improving the collection, documentation, archiving, linking, and dissemination of population representative data sets, especially data sets that are complex, multilevel or multimodal
- Methods for protecting and assuring confidentiality for human subjects when collecting, archiving, linking, or disseminating population-representative data sets, especially data sets that are longitudinal or that include both spatial and individual-level data
- Methods for reducing the costs of collecting, linking, and disseminating large-population-representative data sets
- Development and dissemination of effective tools for prevention research and intervention programs related to STIs/HIV; pregnancy; contraceptive use; adolescent, young adult, and maternal mortality; child health; at-risk youth; and other health-related topics relevant to PDB science
- Innovative approaches and techniques for research design, measurement, and data collection and analysis in the social and behavioral sciences, with particular attention to methodology and measurement issues related to protecting research subjects, archiving and disseminating complex datasets, and studying diverse populations and/or sensitive or confidential behaviors

#### **L. Pregnancy and Perinatology Branch**

The [PPB](#) supports research in the following areas: the physiology of pregnancy and labor; high- risk pregnancies, including those with hypertensive disorders, diabetes or seizure disorders; fetal pathophysiology; premature labor and birth; diagnostic, monitoring, and therapeutic devices and instruments for newborn infants in the nursery and in Neonatal ICU setting; improving the existing products or developing new products that would improve the routine and extended care of the newborn infants; products and agents related to breastfeeding; hospital supplies specifically related to use in the care of newborn infants; nanotechnology and its application for the care of newborn infants; instruments and devices for assessing and monitoring the nursery environment (noise, lighting, and odor); disorders of the newborn; sudden infant death syndrome; and biological and behavioral antecedents of low birth weight.

The following topic areas are of high priority:

- Non-invasive (or minimally invasive) methods to assess preeclampsia; gestational diabetes; fetal well-being; spontaneous preterm birth; and stillbirth
- Methods to characterize the bioactive components of human milk
- Non-invasive methods to longitudinally identify predictors and indicators of placental dysfunction including malperfusion, abnormal placental development, and impaired placental function (nutrient transfer, metabolic function, exchange of respiratory gases, and hormone production).
- Devices, instruments, and tools to minimize bacterial colonization, reduce proclivity for



- thrombus formation, and reduce healthcare associated infection risks
- Lab-on-a-chip; specifically, non- or minimally-invasive approaches for assessing metabolic profiles (e.g., glucose and lactate/pyruvate), ketone bodies, bilirubin (unconjugated, free, indirect, and total), and other major analytes (Na<sup>+</sup> Ca<sup>+</sup> Cl<sup>-</sup> K<sup>+</sup> etc.)
- Rapid methods for diagnosis of bacterial infections and the assessment of antibiotic sensitivity
- Improved syringes, needles, and injection set ups to help administer small doses of medications over prolonged periods (e.g., insulin for treating hyperglycemia)
- Methods to assess pain in the newborn, analgesia, and the evaluation of neonatal opioid withdrawal syndrome
- Non-invasive measures to assess brain energy utilization in the newborn, especially glucose, oxygen, lactate, ketones, and other energy substrates
- Improved devices and instruments for assisted ventilators for use in the neonatal ICU

## M. National Center for Medical Rehabilitation Research

This Center supports innovative research on the restoration, replacement, enhancement or adaptation of function for people with chronic physical disabilities. This includes rehabilitative approaches across etiologies and the lifespan, as well as the environmental and policy factors that promote full participation. We encourage studies that integrate biomedical, engineering and/or psychosocial approaches to develop practical and creative solutions to the daily functioning of people with disabilities and their families. The mission of the NCMRR is to increase the effectiveness of medical rehabilitation practices through research. Information about specific program areas within NCMRR can be found [here](#).

Examples may include but are not limited to:

- **Adaptation and Plasticity:** Develop non-invasive and surrogate measures of plasticity that would be appropriate for use in a clinical setting to target rehabilitation therapies and monitor treatment effectiveness (e.g., biomarkers, imaging)
- **Novel Technology:** Orthotics, prosthetics, and robotics devices and interfaces; Assistive technologies; Invasive and non-invasive biological sensors, prosthetic systems or implants to improve function; New control methods and improved sensory feedback; Strategies for controlling and adapting to the environment; Advanced wheelchair designs and enhancements and other mobility devices; Biomaterials and tissue interfaces, nanotechnology, bionics
- **Rehabilitation Interventions:** Development and use of robotics; Gaming applications; Virtual and Augmented Reality; Simulations; M-health and other approaches to promote participation, understand and support healthy behaviors, reduce health disparities, and enhance clinical compliance, especially in children with physical disabilities.
- **Chronic Symptom Management:** Methods to increase screening for chronic conditions or preventable secondary conditions in individuals with physical disability; Prevention and treatment strategies for mitigating symptoms associated with multiple chronic conditions in individuals with physical impairments, including persistent pain, symptoms of obesity, diabetes, cardiovascular deconditioning, fatigue, symptoms of overuse injuries, pressure ulcers, sleep disturbances, and depressive symptoms; Improving muscle capacity in chronic physical disability to include therapeutic or adaptive exercise and muscle stimulation; muscle-disuse syndromes and contractures; Rehabilitation interventions for improvement of physical disability and comorbid cognitive, sensory, or somatic consequences of impairment, disease or injury; Autonomic function in the context of injury or specific conditions.
- **Rehabilitation in the Community:** Strategies to build or modify community and/or environmental resources that provide effective rehabilitation and health promotion services within the individual's own community. Development of engineering, crowdsourcing, and social science approaches to promote, monitor, and sustain outcomes in real world settings.

Investigators proposing budgets exceeding the guidelines are encouraged to contact program staff six weeks prior to submitting the application.

### **Contact Information**

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For additional SBIR/STTR program administrative information and research topics

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For additional financial/business management questions contact:

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## **NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)**

### **Mission**

NIDA is the lead federal agency supporting scientific research on drug use and its consequences. Our mission is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health through 1) strategically supporting and conducting basic and clinical research on drug use, its consequences, and the underlying neurobiological, behavioral, and social mechanisms involved; and 2) ensuring the effective translation, implementation, and dissemination of scientific research findings to improve the prevention and treatment of substance use and addiction and enhance public awareness of addiction as a brain disorder.

### **Budget Guidance**

Award budgets and project periods are listed in the Section II Award Information of the Omnibus/Parent Notices of Funding Opportunities for SBIR and STTR. Total award budgets include direct costs, indirect costs, and fees and are capped not to exceed the total award amounts listed.

NIDA also sets its budget limits for specific research topics that received a waiver from the U.S. Small Business Administration to exceed the hard budget caps. The current list of approved NIDA topics can be found in the [SBA-Approved Waiver Topics](#). NIDA budget limit for Phase I on SBA-approved waiver topics is \$400,000 in total costs and a project period of up to 1 year. NIDA budget limit for Phase II on SBA-approved waiver topics is \$3,000,000 in total costs and a project period of up to 3 years.

In all cases, applicants should propose a budget and a project duration period that are reasonable and appropriate for the completion of the research project. Applicants are strongly encouraged to contact NIDA program officials early in the application process to receive assistance regarding the program.

### **SBIR and STTR Program Information**

SBIR and STTR programs at NIH are primarily intended to encourage private-sector technology commercialization and increase small business participation in federally funded research and development (R&D). The goal of the NIDA SBIR/STTR program is to increase small business participation and private-sector commercialization of novel products or services that can help manage, prevent, monitor, diagnose, and treat acute substance use, chronic substance use, and substance use disorders.

The NIH/NIDA dual peer review system is mandated by statute. A Scientific Review Group (SRG) composed primarily of non-federal scientists with expertise in relevant scientific disciplines and current research areas carries out the first level of review. The National Advisory Council on Drug Abuse (NACDA) performs the second level of review. Only applications that are recommended for approval by both the SRG and the NACDA may be recommended for funding. Final funding decisions are made by the NIDA Director.

NIDA funding decisions for small business programs are based on a combination of factors:

- Programmatic priorities and current portfolio balance (for funded projects, please search the NIH RePORTER database at <https://reporter.nih.gov/>)
- Potential for commercialization and public health impact;
- For Phase II applications: results of Phase I (or equivalent) clearly indicating that both technical feasibility and commercial feasibility were established, and the scientific merit and commercial potential of the project proposed in Phase II;
- For applicants who received preceding SBIR and STTR grants: quality of prior performance and evidence of Phase III activities;

- Peer review critiques and overall impact score;
- Security risk, as assessed by the HHS Due Diligence Program;
- Availability of funds.

### **Disclosure Requirements Regarding Ties to Foreign Countries**

(<https://seed.nih.gov/small-business-funding/small-business-program-basics/foreign-disclosure-and-risk-management>)

Applicants to the SBIR and STTR programs are required to disclose all funded and unfunded relationships with foreign countries, using the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form (hereafter referred to as the SBIR STTR Foreign Disclosure Form), for all owners and covered individuals. Applicants who do not submit the completed SBIR STTR Foreign Disclosure Form during the NIDA JIT process will not be considered for funding. Details of the SBIR and STTR Foreign Disclosure and Risk Management Pre-award and Post-Award Requirements can be found in NOT-OD-24-029.

### **NIDA-specific SBIR and STTR Program Information**

NIDA is the largest source of initial funding for research efforts to address the needs of acute substance use, chronic substance use, and substance use disorder (SUD) markets, undertaken with the goal of commercialization. Commercialization is a process of delivering new products or services into the market. Historically, the engagement of large private biomedical enterprises in the SUD space was limited. Therefore, NIDA is devoted to achieving meaningful impact through enabling small businesses and startups to commercialize substance use and drug addiction products, services, or technologies. NIDA acknowledges the importance of project management in successful new product development and encourages the use of project management tools and terms by the grant applicants.

The SBIR and STTR programs are phased programs:

Phase I: Supporting Feasibility and Proof of Concept. The objective of this phase is to establish the technical and commercial feasibility of the proposed research or R&D efforts and to determine the quality of performance of the applicant (small business concern or SBC) before providing further federal support in Phase II.

Phase II: Supporting Research and Development. The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding will be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.

Phase III. The objective of Phase III is for the small business concerns (SBC) to pursue commercialization objectives resulting from the Phase I/II R&D activities. A Phase III is defined as an award that derives from, extends, or completes prior SBIR effort and is funded with non-SBIR funds. NIDA encourages grantees to seek commitment(s) of funds and/or resources from an investor or partner organization for the commercialization of the product(s) or service(s) resulting from the SBIR/STTR Phase I/II grant. Phase III funding may come from different sources: private investors, venture capital firms, strategic alliances, research contracts, sales of prototypes, public offerings, state finance programs, non-SBIR-funded R&D, or production commitments from industrial firms or a federal agency for use by the U.S. government. NIDA monitors SBC efforts to pursue, with non-SBIR/STTR funds, the commercialization of Phase I and II outputs.

While both the SBIR and STTR programs are organized to provide government funding only in Phase I and Phase II, NIDA is committed to assuring that its grantees are also prepared to successfully execute Phase III.

### ***Feasibility and Milestones***

This section provides additional requirements and instructions which relate to definitions of the terms “feasibility” and “milestones” for NIDA-specific applications, as well as addressing funding for assistance in developing and executing in these areas.

### Feasibility

To improve the odds of reaching Phase III, NIDA suggests using a simple desirability-feasibility-viability (DFV) framework. While envisioning the goal for the Phase I project, NIDA applicants are encouraged to address both technical feasibility (e.g., “can this offering [product or service] be built?”) and commercial feasibility (e.g., “should this offering be built?”), which may include the initial explorations into desirability (e.g., “does anyone want or need this offering?”) and viability (e.g., “how can financial stability be assured?”).

It is important to understand the resources that NIH allows to establish commercial feasibility. The NIH Grant Policy (see section 18.5.5.1 Market Research), states that “*NIH will not support market research, including studies of the literature that lead to a new or expanded statement of work*”, under the SBIR or STTR grant, with the exception of Technical and Business Assistance (TABAs) funds (see “Technical and Business Assistance (TABAs)” section below). The policy defines market research as follows: “*For purposes of the SBIR/STTR programs “market research” is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the proposed research. It includes various types of research, such as the size of potential markets and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, “market research” does not include activities under a research plan or protocol that include a survey of the public as part of the objectives of the project to determine the impact of the subject of the research on the behavior of individuals*”.

### Milestones

In NIDA small business grant applications, a clear understanding of the term “milestone” needs to be demonstrated. In project management, the milestone is used to define an important decision point at which significant uncertainty for a given project is resolved. The quest to conduct research activities to establish technical and commercial feasibility should culminate in reaching a significant milestone. The NIH SF424 (R&R) Application Guide instructs the applicants to include milestones for every Phase I, Phase II, Fast Track and SBIR direct to Phase II applications, as these will be used in the evaluation process. Milestones are evaluated as part of Approach and Investigator(s) review criteria. Missing or inadequate technical and commercial milestones can therefore negatively affect the application’s impact score.

In NIDA small business applications, NIDA expects meaningful milestones and milestone deliverables, associated with each milestone. Specific Aims and milestones are related but distinct elements in the application. As stated by the SF424 (R&R) Application Guide, Specific Aims are goals, specific objectives, and expected outcomes of the proposed research. These Specific Aims are the activities that enable a company to reach a milestone (go / no-go decision point). Each Specific Aim in the application should therefore have at least one milestone associated with it.

Moreover, milestones, e.g. decision points, are tied to deliverables which are always tangible. Accordingly, NIDA expects its awardees to identify meaningful milestones and to develop tangible deliverables associated with each milestone that are specific, measurable, achievable, relevant, and time-bound. These can be written in the following format:

- *Milestone A...*
  - *Specific Aim A...*
    - *Milestone Deliverable A (specific, measurable, achievable, relevant, time-bound)...*

For example,

To establish **Technical feasibility** for a drug discovery and development project:

*Milestone 1: In-vitro* assay validation for SAR studies

*Specific Aim 1:* Validate and optimize *in vitro* assays (Potency and Selectivity)

*Milestone deliverable 1 (specific, measurable, achievable, relevant, and time-bound):* Within 2 months, achieve Z' factor of  $\geq 0.5$ , based on values from at least 1/2 plate of positive and negative controls.

*Milestone deliverable 2 (specific, measurable, achievable, relevant, and time-bound):* Within 4 months, demonstrate that concentration response testing over at least 8 concentrations generates reproducible IC50 values withing a 3-fold range for 3 standard compounds.

To establish **Commercial feasibility** for a medical device development project:

*Milestone 1:* Payor Feedback

*Specific Aim 1:* Obtain payor feedback regarding requirements for coverage and reimbursement.

*Milestone deliverable (specific, measurable, achievable, relevant, and time-bound):* Within 3 months of receiving the NIDA Notice of Grant Award, initiate the contact with The FDA CDRH Early Payor Feedback Program (EPFP) and submit EPFP Overview Request; meet with at least 3 payors to obtain feedback about clinical study design and proposed endpoints necessary to obtain payor coverage.

## **Fast-Track Application**

The NIH Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. It expedites award decisions and funding of SBIR and STTR Phase II applications for scientifically meritorious projects that have a high potential for commercialization. Fast-Track applications receive a single rating. Before submitting applications for Fast-Track review, applicants are strongly encouraged to consult with NIDA program staff to assure that Fast-Track is appropriate. NIDA encourages Fast-Track mechanisms for those applications for which a high potential for commercialization is established. For its Fast-Tracks, NIDA also encourages preliminary data that clearly supports technical and commercial feasibility. If repurposing already-existing drugs or devices for SUD diagnosis or treatment, preliminary data about existing drug/device and scientific rationale for the feasibility in the SUD space is required. In addition, NIDA requires a commercialization plan that demonstrates a high probability of commercialization and letters of Phase III support/interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources. Letters of interest from potential commercial partners or investors and letters of commitment of funds or other resources that will enhance the likelihood of commercialization should be placed following the letters of support for consultants and collaborators.

Importantly, before Fast-Track Phase II could start, NIDA conducts an administrative review and evaluates the achievement of the stated milestones. In addition to Approach and Investigator(s), Fast-Track milestones are assessed in the peer review under Additional Review Criteria: Does the phase I applications specify milestones that should be achieved prior to initiating Phase II? Applicant's failure to provide milestones and specific, measurable, achievable, relevant, and time-bound milestone deliverables may be sufficient reason for the peer review to exclude the application from the Fast-Track review.

Fast-Track applicants must propose two separate sets of milestones and associate them with specific, measurable, achievable, relevant, and time-bound milestone deliverables, one set for Phase I and another set for Phase II. The timelines for milestone deliverables are to be completed sequentially. It is important to clearly state the go / no-go milestones that will determine a transition to Phase II. Failure to adequately address these criteria may negatively affect the application's impact score. The following format is encouraged:

## Phase I

- o *Specific Aim A...*
- *Milestone Deliverable A (specific, measurable, achievable, relevant, time-bound)...*  
*Phase I Milestone A (go/no-go, pivot)*

## Phase II

- o *Specific Aim A...*
- *Milestone Deliverable A (specific, measurable, achievable, relevant, time-bound)...*  
*Phase II Milestone A...*

Based on peer review recommendations, NIDA Program Officers may negotiate the Phase I milestones with applicants and potential Fast-Track awardees before they are included in the terms of the award. Fast-Track applications will receive a secondary review by the NIDA advisory council. Phase II applications will be selected for funding based on NIDA's assessment of the Phase I progress, and determination that the Phase I milestones were achieved; an update and verification of the Commercialization Plan and any commitment(s) for funds and/or resources from an investor or partner organization, the project's potential for meeting the mission of NIDA and for commercial success; and the availability of funds. NIDA may find it appropriate for an outside reviewer(s) to be involved in the process of administrative review. If NIDA staff determines that the progress has not been adequate during Phase I, additional information may be requested. Because of the intricacy of the Fast-Track mechanism, NIDA staff invites open communication with applicants regarding this complex mechanism. NIDA staff will monitor program progress against proposed milestones and make non-competing award decisions based on achieving milestones. If NIDA program staff determines that progress in Phase I has not been adequate, milestones were not met, and the Fast-Track Phase II is not recommended for funding, that decision is not appealable.

### Technical and Business Assistance (TABA)

NIDA informs its applicants about additional capabilities that may assist in establishing technical and commercial feasibility through the dedicated TABA funding. Through TABA, small business applicants may request up to \$6,500 per year for a Phase I project and up to \$50,000 across all years for a Phase II project to help address the development and commercialization of their new products and processes resulting from such projects, including intellectual property protections. TABA funding could be requested to assist with product sales, intellectual property protections, market research and/or validation, development of regulatory or manufacturing plans, and access to technical and business literature available through online databases. Importantly, TABA activities are conducted externally, and, if NIDA applicants wish to utilize the outside TABA provider/vendor that is not associated with the small business applicant, they are required to include the vendor as a consultant in the budget and to provide a detailed budget justification. All instructions in the SF424 (R&R) Application Guide must be observed. Fast-Track applications are a combination of both Phase I and Phase II and small businesses can request TABA funding in both phases within their Fast-Track application up to these amounts for each phase. NIDA does not allow requesting TABA funding through an Administrative Supplement.

### Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIDA does not participate in the CRP program. NIDA will not accept Phase IIB applications through the Omnibus or specific program announcements.

### Specific Funding Opportunities and Programs Translational Research



NIDA offers additional funding opportunities and programs to accelerate the preclinical discovery and development of new medical products for SUD patients, including pharmacotherapeutics and medical diagnostic and therapeutic devices.

**Blueprint MedTech:**

(<https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-medtech/blueprint-medtech>)

The program aims to support innovators by accelerating the development of cutting-edge medical devices to diagnose and/or treat disorders of the nervous system. The program provides: (a) non-dilutive funds to support medical device development activities led by investigators, and (b) additional resources and support services.

Contact: Leonardo Angelone, PhD, Blueprint MedTech Program Lead ([leonardo.angelone@nih.gov](mailto:leonardo.angelone@nih.gov))

**Blueprint Neurotherapeutics Network (BPN) for small molecules:**

(<https://neuroscienceblueprint.nih.gov/neurotherapeutics/bpn-small-molecules>)

The program provides both non-dilutive funding and additional resources for small molecule drug discovery and development, from hit-to-lead chemistry through phase I clinical testing. The program offers funding, access to NIH-funded contract research organizations (CROs), and access to consultants with expertise in various aspects of drug discovery and development.

Contact: Elena Koustova, PhD, MBA, Director, NIDA Office of Translational Initiatives and Program Innovations ([koustovae@nida.nih.gov](mailto:koustovae@nida.nih.gov))

Both programs utilize the cooperative agreement (U44) mechanism, which is milestone-driven and involves NIH program staff participation in developing the project plan, monitoring research progress, and appropriate go/no-go decision-making. SBIR applicants considering projects involving translational research are strongly encouraged to contact program staff well in advance of submission.

**Clinical Trials**

Does NIDA accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NIDA accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	NIDA accepts and supports SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NIDA Funding Opportunities webpage: <a href="https://nida.nih.gov/funding">https://nida.nih.gov/funding</a>
Does NIDA support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	NIDA accepts and supports non-SBIR/STTR clinical trial applications through specific opportunities, which can be found on the NIDA Funding Opportunities webpage: <a href="https://nida.nih.gov/funding">https://nida.nih.gov/funding</a>

**Research Topics**

The major NIDA SBIR/STTR portfolio areas of interest are listed below as a general guide. Applications proposing innovative technologies in substance use and addiction with strong commercial potential that fall outside these portfolio areas are also encouraged through this Omnibus solicitation.

1. **Biomarker Development for SUDs**
2. **Personalized Medicine for SUDs**
3. **SUD Drug Discovery and Development**
4. **FDA-regulated Medical Therapeutic and Diagnostic Devices for Substance Use and Addiction**
5. **Harm Reduction Technologies**

## **6. Technological Approaches to Decrease Stigma Associated with Substance Use and Addiction**

### **7. Prevention Technology to Address Substance Use and Addiction in Various Underserved Populations**

#### **Biomarker Development for SUDs**

Currently, there are no biomarkers to assess or predict treatment efficacy or categorize SUDs into clinical subtypes. Thus, it is impossible to design treatments for effective and long-term recovery by classifying SUD patients into categories that have reproducible and predictive validity.

Long-term use of opioids and other substances alters the integrity of homeostasis, changing the endogenous opioid, endogenous cannabinoid, and almost all receptor systems studied so far in the brain and peripheral immune cells. Biomarkers and signatures in patients diagnosed with an SUD can be very different from those observed in patients without SUDs. These biomarkers or potential predictive markers could serve as objective prognostic indicators to develop SUD. In addition, they could act as response predictors to SUD therapeutics in adults, or as diagnostic biomarkers for infants with neonatal abstinence syndrome (NAS). Furthermore, artificial intelligence (AI)-related technologies are being investigated in healthcare to analyze patients' big data, such as electronic health records of historical and current patient treatments, to create more effective and better patient outcomes and to identify new diagnostic tools and novel analyses. Accordingly, AI-related tools are of interest to accelerate traditional and innovative areas of SUD biomarker development.

The proposed biomarker research should emphasize the importance of biomarker signatures that can intersect SUD and related conditions that are considered important to the mission of NIDA. Proposed projects may include biomarkers that assess the probability of SUD or allow an assessment of the treatment trajectory in patients under treatment for SUD. Specific projects may encompass, but not restricted to:

- Biomarkers with high specificity and sensitivity for opioids, stimulants, cannabis and other emerging substances;
- Biomarkers that can detect substance use in early stage;
- Development of biomarkers that provide objective measures of substance use.
- Biomarkers that can predict an individual's response to different treatment modalities.
- Biomarkers suitable for longitudinal monitoring of substance use.
- Biomarkers capable of detecting concurrent use of multiple substances

Projects solely focused on biomarkers for pain and alcoholism are of limited interest.

#### **Personalized Medicine for SUDs**

Advancements in technology and our deepening understanding of underlying neurobiology have provided us with the chance to target specific neurobiological processes and tailor interventions approaches to individual patients based on their unique genetic, neurobiological, and environmental characteristics. This personalized approach recognizes the significant variability among individuals in how they respond to medications, therapies, and other interventions. Genetic variations can influence a person's susceptibility to developing SUD, and treatment response. Genetic testing would identify specific gene variants associated with SUD risk, metabolism of drugs and treatment response. Further, neurobiological differences in brain structure and function can impact how an individual's experiences and respond to different substances. Identifying aberrant brain connectivity patterns and assessing neurotransmitter levels can guide the treatments to modulate the pathways. Finally, social, cultural, and environmental factors play a significant role in the development and course of SUDs. Areas of interest include but are not limited to: a) Identifying and leveraging existing social support networks and recognizing environmental triggers that contribute to substance use and modifications to mitigate the impact and b) utilizing big-data analytics and predictive modeling to identify patterns and predictors of treatment response and refine personalized treatment approaches. Overall, personalized medicine holds promise for improving the

effectiveness and outcomes of SUD treatment by addressing the biological and social factors that contribute to substance use disorders.

### **SUD Drug Discovery and Development**

Pharmacotherapy offers an important means of treating SUDs. Currently, there are five pharmacotherapies approved by the Food and Drug Administration (FDA) for the treatment of Opioid Use Disorder (OUD) and mitigation of opioid withdrawal symptoms: methadone, buprenorphine, extended-release naltrexone, naloxone, and lofexidine. In addition, varenicline is an approved drug for the treatment of nicotine cessation. However, given the diverse nature of SUDs, many patients have limited responses to available medications and, consequently, there is an urgent need for novel treatments. It remains of program interest to identify and develop improved pharmacotherapeutics with clear advantages over our current approved pharmacotherapeutics for OUD treatment and for nicotine cessation treatment. Additionally, there are no FDA-approved medications for cocaine, methamphetamine, or cannabis use disorders.

Broadly, novel pharmacotherapeutics are encouraged for the range of unmet medical needs in SUD, for polysubstance use, and for emerging novel treatment modalities and mechanisms of action for SUD treatments. Developing and evaluating new, more efficacious medications remains a high priority.

Candidate medications may include either novel or re-purposed compounds.

Specific areas of interest include medications that target one or more domains of the addiction cycle, including reward, stress and negative affect, incentive salience, executive function, habituation, and impulsivity/compulsivity. Proposed projects may include emerging technologies and platforms for SUD medication development with a focus on products with the potential to minimize drug seeking, compulsive behavior, overdose prevention, and reversal. Specific projects may include, but are not limited to:

- Early therapeutic discovery activities ranging from target identification and validation through lead development;
- SUD phenotypic assay development (e.g., organoids, organ-on-a-chip technologies, and higher content invertebrate models, ex vivo bioassays) with validation studies in animal models (e.g., rodent models).
- Preclinical and/or clinical drug development;
- Medications that would address specific symptoms of withdrawal, such as cravings, depression, cognitive impairments, pain, and sleep problems;
- Medications (neurochemicals) involved in social bonding that also modulates key processes associated with addiction, including reward and stress responses, and may enhance the efficacy of psychosocial addiction treatments;
- Big-data analytics and machine-learning algorithms analysis yielding insight into behavioral and biological markers of relapse risk;
- Artificial Intelligence (AI)-related tools in SUD drug discovery and development to increase innovation and support a cost- and time-effective SUD drug development of pharmacotherapies.
- Combination of pharmacotherapeutics to improve SUD treatment adherence and decrease risk of relapse. Molecules may include new and investigational compounds and repurposed approved medications

Projects proposing to study compounds already extensively investigated or currently being studied in patients with SUD, and projects solely focused on pain or on alcoholism not associated with SUD are of limited interest.

### **FDA-regulated Medical Therapeutic and Diagnostic Devices for Substance Use and Addiction**

Medical Devices, including Software as Medical Device (SaMD), offer promising means to monitor, diagnose, and treat patients who use substances for medical purposes, in addition to patients with SUDs.

Currently, there are only a few devices that are cleared by the FDA for the treatment of SUD. As such, the investigation and development of new safe and effective medical devices intended to prevent, monitor, diagnose, and treat substance use and addiction is a high priority. Applications in this area are expected to address the needs of those who actively use substances, chronically use substances, or have a diagnosed SUD, and their caregivers, to ensure access to high-quality, safe, and effective medical devices. It is expected that proposed approaches will include activities that will lead to regulatory submissions for pre-market clearance / approval, including interactions with the FDA via the following pathways: pre-submission (Q-submission), Investigational Device Exemption, 510(k), DeNovo, or Premarket Approval (PMA) application. Additional pre-clinical activities may include, but are not limited to, a) bench testing or computational modeling studies; b) good laboratory practice animal studies; c) good manufacturing practice studies; d) toxicology and biocompatibility studies; e) software verification and validation; f) usability/user experience testing.

Specific areas of interest include, but are not limited to:

- Imaging devices intended to investigate brain function and enhance monitoring, diagnosis, and/or treatment of SUD;
- Devices that directly diagnose and/or reduce craving and withdrawal symptoms;
- Devices that identify and/or treat NAS;
- SaMD focused on behavioral health interventions to alleviate the burden of SUD;
- Therapeutic devices (e.g., neuromodulation) intended to improve SUD treatment outcomes and relapse prevention;
- Physiological monitoring devices, including remote detection (e.g., wearables, sensors, health monitoring/emergency notification systems), specifically intended for use in patients affected by substance use and addiction.

### **Harm Reduction Technologies**

Harm reduction is an evidence-based public health approach that directly engages people who use drugs (PWUD) to prevent overdose, disease transmission, and other harms associated with drug use. NIDA included harm reduction in its FY 2022-2026 Strategic Plan in Priority Scientific Area #2: Develop and Test Novel Prevention, Treatment, Harm Reduction, and Recovery Support Strategies. Harm reduction was also identified as a federal drug policy priority in the 2022 National Drug Control Strategy from the White House Office of National Drug Control Policy (ONDCP) and is also one of the strategic priorities of the U.S. Department of Health and Human Services (HHS) Overdose Prevention Strategy. Decades of evidence has shown that strategies for harm reduction substantially reduce HIV and hepatitis C infection among people who inject drugs, reduce overdose risk, enhance health and safety, and increase the likelihood of PWUD to initiate substance use disorder (SUD) treatment (SAMHSA Harm Reduction Framework 2023).

The ideology behind harm reduction is based on helping PWUD increase their quality of life even if they are not yet ready to enter treatment. The ONDCP's Guiding Principles on Harm Reduction are: 1) supporting individuals and overcoming obstacles in accessing all types of care, from overdose prevention strategies to medications and mental health services, 2) providing ongoing support to individuals once harm reduction or treatment services are initiated, 3) creating connections for PWUD with caring staff or volunteers as part of receiving health and social services, and 4) treating PWUD with respect and dignity to help them achieve better outcomes. Harm reduction strategies can address safer practices, safer settings, access to healthcare, transitions to care, sustainable infrastructure, and a sustainable workforce.

Applications addressing harm reduction principles include, but are not limited to, technologies for:

- Education about the value of harm reduction and reduction of stigma surrounding drug use;

- Prevention, treatment, recovery, and general health promotion for PWUD;
- Addressing overdose education, detection, and naloxone use;
- Promoting safer use (e.g., drug-checking, reducing infection risk);
- Prevention, testing, and treatment for sexually transmitted infections;
- Ensuring access to and assistance with nutrition, clothing, shelter, housing;
- Enabling peer support and the inclusion of people with lived experience in all aspects of care;
- Increasing access to low-barrier treatment services, including access to healthcare and oral health services;
- Ensuring access to medication and treatment on-demand, including mobile buprenorphine and methadone;
- Expanding telehealth and addressing low technology literacy;
- Ensuring coordination of care for individuals leaving carceral settings.

### **Technological Approaches to Decrease Stigma Associated with Substance Use and Addiction**

Stigma is understood as a socially constructed phenomenon that occurs when members of a group experience status loss or discrimination based on some shared characteristic that is deemed undesirable by others. Its effects can occur through attitudes and beliefs internalized by impacted individuals (self-stigma), through overt discrimination by others (experienced or enacted stigma), and through the fear of such discrimination (felt stigma). The stigma around substance use and addiction represents a significant public health problem, despite the growing understanding that substance use and addiction are complex brain disorders with behavioral and physiological components. As for other disorders, medical care is often necessary to facilitate recovery and prevent adverse outcomes, including overdose. Patients can recover from substance use and addiction and lead healthy lives; however, stigma limits successful access to care. Stigma often may be related to multiple conditions, such as SUD, mental illness, or infectious disease; behaviors such as specific drug use practices (e.g., opioid injection); or identity statuses related to gender, sexual orientation, sexual identity, race/ethnicity, or socioeconomic factors, such as personal income. It is expected that leveraging state-of-the-art technologies and the latest science will allow to develop and commercialize the products and services aimed at reducing the stigma around substance use and addiction.

Applications in this topic may propose projects demonstrating how latest technology and evidence-based science could meaningfully reduce the stigma associated with substance use and addiction. Applications may address individual (internalized, anticipated, or enacted), interpersonal, organizational, and/or structural levels of stigma.

Applications and focus can be on any entry point along the continuum of care. Areas of specific research interest and substance use and addiction service contexts include, but are not limited to:

- Providing anti-stigma training for medical professionals;
- Targeting stigma reduction of non-medical providers (social workers, criminal justice, family members, and educators);
- Enhancing both employee well-being and effectiveness of a drug-free and stigma-free workplace program;
- Anti-stigma training specific to adolescent substance use and prevention;
- Digital certification program for nonprofessional care givers who provide support services for patients with SUD;
- Virtual employee assistance programs with focus on SUD and mental health.

Additionally, examples of technological approaches include, but are not limited to:

- Natural language processing, computer vision, and other machine learning tools to detect and analyze provider behaviors and medical records reflecting stigma around substance use and addiction alone and intersectional stigma;
- Digital compassion (anti-stigma) coaching for medical professionals delivering treatment to SUD patients exploring immersive technologies such as extended reality;
- Ecological momentary sampling and other digital phenotyping patient-centered tools to detect points of vulnerability and counteract internal stigma supporting the whole-person model of recovery;
- Neural activity-based tools and services to help develop and disseminate the most effective anti-stigma campaign.

### **Prevention Technology to Address Substance Use and Addiction in Various Underserved Populations**

Differences in race, socioeconomic status, sex, and geography have created inequities in care for substance use and addiction. Alternatives in healthcare that emerged during the pandemic, such as virtual doctor visits, along with new tools to facilitate telehealth, may help address some of the barriers to SUD care for currently underserved populations.

There are three categories for which prevention technology can address substance use and addiction in various underserved populations despite the aforementioned differences. Primary prevention provides tools to intervene before health effects occur. Secondary prevention provides screening tools to identify diseases in the earliest stages before the onset of signs and symptoms. Tertiary prevention provides tools to manage disease post-diagnosis to slow or stop disease progression.

Applications may address micro- (individual, internalized, anticipated, or enacted), or macro- (interpersonal, organizational, and/or structural) levels of health inequities related to various underserved populations. The focus of applications can be on any entry point along the continuum of substance use and addiction care. Examples include:

- Primary prevention through measures such as altering risky behaviors (cannabis and/or tobacco use), and banning substances known to be associated with a disease or health condition.
- Secondary prevention through measures such as SBIRT (Screening, Brief Intervention, Referral to Treatment).
- Tertiary prevention through measures such as rehabilitation, and medication assisted therapy.

Areas of specific research interest with respect to substance use and addiction service contexts include, but are not limited to:

- Providing prevention education and behavior change training for medical professionals; targeting knowledge awareness and behavior change for non-medical providers (social workers, criminal justice, family members, and educators);
- Digital or non-digital behavior change interventions enhancing both employee well-being and effectiveness of a drug-free workplace program;
- Digital or non-digital prevention education training specific to adolescent substance use and prevention;

Additionally, examples of technological approaches include, but are not limited to:

- Machine learning tools (e.g., natural language processing) for provider/medical record substance use and addiction bias;

- Digital mindfulness coaching for medical professionals delivering substance use and addiction services with virtual reality;
- Ecological momentary sampling and other digital phenotyping patient-centered tools to detect points of vulnerability and address them with a whole-person model of recovery.

### **Contact Information**

**Prior to Submission:** Applicants are strongly encouraged to request a technical assistance meeting with NIDA SBIR/STTR staff prior to submitting any application. To schedule a meeting, please email:

Ernestine Lenteu  
 Program Specialist  
 NIDA Office of Translational Initiatives and Program Innovations  
[NIDASBIR@mail.nih.gov](mailto:NIDASBIR@mail.nih.gov).

**For additional information on research topics, please contact a Program Officer with the relevant area of expertise:**

Leonardo Angelone, PhD  
 Program Officer  
 Email: [leonardo.angelone@nih.gov](mailto:leonardo.angelone@nih.gov)  
*Areas of expertise: FDA-regulated therapeutic and diagnostic devices for substance use and addiction.*

Morris Flood, DHSc  
 Program Officer  
 Email: [morris.flood@nih.gov](mailto:morris.flood@nih.gov)  
*Areas of expertise: Consumer products and approaches that address the health-related social needs that impact substance use and addiction; and digital health technology translation to commercial substance use and addiction products that address the overall social determinants of health.*

Stacie Gutowski, PhD  
 Program Officer Email: [stacie.gutowski@nih.gov](mailto:stacie.gutowski@nih.gov)  
*Areas of expertise: FDA-regulated therapeutic and diagnostic devices for substance use and drug addiction, including neuromodulation.*

Saravanan Karuppagounder, PhD  
 Program Officer  
 Email: [saravanan.karuppagounder@nih.gov](mailto:saravanan.karuppagounder@nih.gov)  
*Areas of expertise: Therapeutics for Stimulant Use Disorders and Marijuana or Cannabis Use Disorder, Biomarker Development and Validation.*

Yordan Kostov, PhD  
 Program Officer  
 Email: [yordan.kostov@nih.gov](mailto:yordan.kostov@nih.gov)  
*Areas of expertise: FDA-regulated monitoring and diagnostic devices for substance use and addiction, including target-agnostic detection.*

Tam Nguyen, PhD  
 Program Officer  
 Email: [tam.nguyen@nih.gov](mailto:tam.nguyen@nih.gov)  
*Areas of expertise: Pharmacotherapeutics for opioid use disorder, overdose reversal, and smoking cessation.*

Boris Sabirzhanov, PhD

Program Officer

Email: [boris.sabirzhanov@nih.gov](mailto:boris.sabirzhanov@nih.gov)

*Areas of expertise: Helping to End Addiction Long-term (HEAL) initiative.*



# NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

## Mission

The NIDCD supports research on the normal mechanisms of, as well as on diseases and disorders of hearing, balance, smell, taste, voice, speech and language. The Institute also supports research related to disease prevention and health promotion. The NIDCD addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. The NIDCD also supports efforts to create and refine devices, as well as develop cellular-based applications that may replace or substitute for lost and impaired sensory and communication functions. For more information about areas of interest, please visit our home page at <http://www.nidcd.nih.gov/> and the NIDCD Strategic Plan website (<https://www.nidcd.nih.gov/about/strategic-plans>). Potential applicants are encouraged to contact the program staff noted below early in the process of preparing the application.

## Budget Guidance

Total funding (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting the application. The Small Business Administration has allowed NIDCD to make awards that exceed these amounts for the areas noted in the [SBA-Approved Waiver Topics](#). For topics listed in the [SBA-Approved Waiver Topics](#), the NIDCD generally will not fund Phase I applications greater than \$385,000 total costs or Phase II applications greater than \$3,000,000 total costs. All applications must contain sufficient detail to justify the requested budget, and NIDCD may decrease the length of an award and/or the budget as recommended by a review committee or administrative review.

## Specific SBIR and STTR Program Information

NIDCD will accept applications for support of clinical trials in any of the areas noted above.

NIDCD does not accept applications for Phase IIB competing renewal awards.

NIDCD participates in the [SBIR/STTR Commercialization Readiness Pilot \(CRP\) Program](#).

## Clinical Trials

Does NIDCD accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NIDCD accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does NIDCD support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	NIDCD accepts and supports non-SBIR/STTR clinical trial applications through specific opportunities, which can be found on the NIDCD Funding Opportunities webpage: <a href="https://www.nidcd.nih.gov/research/clinical-studies/researchers-professionals/know-what-is-available">https://www.nidcd.nih.gov/research/clinical-studies/researchers-professionals/know-what-is-available</a>

## **Research Topics**

The NIDCD accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Some examples of research topics within the NIDCD mission areas include topics shown below; further example can be found on the NIDCD Strategic Plan website (<https://www.nidcd.nih.gov/about/strategic-plans>).

Priority is given to meritorious applications that are likely to develop innovative technologies, provide clear evidence of effectiveness, and bring novel products to the commercial marketplace.

### **Hearing and Balance Program**

Development of treatment modalities to prevent or lessen the effects of hearing disorders; development of new hearing aids, over the counter hearing aids, cochlear implants, and other assistive devices; development of improved screening technologies to assess hearing loss, in adults as well as in neonates and infants. Development of technologies that provide self-fitting, self-adjusting, or other features that increase performance, accessibility, or affordability of hearing aids; development of new outcome measures for assessing the efficacy of treatments for hearing disorders. Development of technologies for the diagnosis and treatment of tinnitus. Development of technologies for the diagnosis and treatment of otitis media including non-invasive diagnostics to identify middle ear pathogens, novel antibacterial strategies, and prophylactic anti-microbial strategies. Development of technologies for the study, diagnosis and treatment of noise-induced and age-related hearing loss.

Development of technologies for the study, diagnosis and treatment of balance disorders, particularly for the elderly; development of clinical tests and instruments to assess balance/vestibular function; development of instruments and tests measuring head stability and vestibular function during natural stimulation of the vestibular system; development of perceptual reporting techniques and psychological indices for clinical assessment of the balance-disordered patient; development of tests and new outcome measures for assessing the efficacy of physical rehabilitative regimens for balance disorders; and development of assistive devices for balance disorders, including neural prostheses for the vestibular system.

Development of new research tools to aid in the study of the auditory and/or balance systems that can provide an improved understanding of fluctuating patterns of neural circuit structure and function over time and across large assemblies of neurons; new animal models of impaired function; improved diagnostic tools for inner ear function, including DNA-based assays and biochemical markers of disease; innovative tests and instruments to screen for and diagnose inner ear function. Development of technologies to enable gene transfer to the inner ear, including viral vectors and cell type specific markers and probes to examine cell lineage in inner ear regeneration. Development of innovative *in vivo* imaging capabilities to significantly advance visualization, diagnosis, and treatment of disorders in the clinic.

### **Voice, Speech, and Language Programs**

NIDCD is interested in the development of technologies for the study of communication disorders: nature, causes, diagnosis, treatment, and prevention. These communication disorders include but are not limited to: aphasia, apraxia, developmental language disorders, dysarthria, dysphonia, and stuttering. In addition, research is needed for communication challenges that may accompany individuals with autism, deafness, hearing loss, or the inability to rely on spoken language as a primary means of communication. NIDCD is particularly interested in projects that employ a user-centered design or similar approach that engages the target end user throughout the development and research process. In addition, these technologies should be accessible to culturally and linguistically diverse populations.

The emphasis of responsive projects may include the development of technologies such as: augmentative and alternative communication (AAC) devices; assistive device enhancements that better simulate natural speech (e.g. age, gender, emotion); brain computer interface (BCI) communication prosthesis; mobile health applications; gender affirming voice care; flexible and adaptable treatment delivery systems or intervention protocols that can be easily tailored to the needs of an individual; improved artificial larynges and tracheoesophageal shunts; artificial intelligence computer models that simulate normal and disordered communication; virtual/augmented reality approaches to treatment; and technologies that assist in the access to or delivery of healthcare during a public health crisis.

### **Taste and Smell Program**

Development of easily administered diagnostic tools for testing human chemosensory function throughout the lifespan; development of intervention strategies and targeted drugs for the treatment of taste and smell disorders; preventive measures to limit the harmful effects of infections, airborne toxins, radiation, chemotherapy and other drugs on chemosensory function; novel therapies to stimulate regeneration of mature sensory neurons in damaged and/or aged tissue; development of biomarkers for neurodegenerative disease; development of tools to facilitate chemosensory research including improved neuroimaging techniques and visualization at structural and cellular levels.

### **Contact Information**

For administrative and business management questions, contact:

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### **Voice & Speech Program**

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# NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

## **Mission**

The NIDCR advances fundamental knowledge about dental, oral, and craniofacial (DOC) health and disease, and translates these findings into prevention, early detection, and treatment strategies that improve overall health for all individuals and communities across the lifespan. For more specific information about areas of interest to the NIDCR, please visit our home page at <http://www.nidcr.nih.gov>.

NIDCR's small business programs are highly focused on maximizing translational science opportunities – moving rapidly and translating basic dental and orofacial discoveries into useful products.

## **Budget Guidance**

Total funding (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting the application. The Small Business Administration has allowed NIDCR to make awards that exceed these amounts for the areas noted in the [SBA-Approved Waiver Topics](#). All applications must contain sufficient detail to justify the requested budget, and NIDCR may decrease the length of an award and/or the budget as recommended by a review committee or administrative review.

## **Specific SBIR and STTR Program Information**

### **Special Statement regarding clinical trials:**

NIDCR does not support clinical trials through SBIR/STTR programs. Small business concerns proposing a clinical trial must use the UG3/UH3 program. Projects seeking to propose technology validation studies within SBIR/STTR applications that involve human subjects research must provide a detailed justification describing that the funds available through these awards can adequately support the proposed human subject study especially if the study is testing a drug, device or biologic in support of an investigational new drug (IND) or investigational device (IDE) application.

## **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIDCR does not accept Phase IIB renewal applications. NIDCR participates in the CRP program but does not support clinical trials through the CRP program.

## **Clinical Trials**

Does NIDCR accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No	
Does NIDCR accept Clinical Trials through specific Notices of Funding Opportunities?	No	

Does NIDCR support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<a href="#">NIDCR Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3 Clinical Trial Required) and subsequent reissues</a> <a href="#">NIDCR Behavioral and Social Intervention Clinical Trial Planning and Implementation Cooperative Agreement (UG3/UH3 Clinical Trial Required) and subsequent reissues</a>
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## **Research Topics**

### **Translational Developmental Biology and Mammalian Genetics and Genomics**

Priorities are to 1) understand the development of craniofacial complex and 2) elucidate the mechanisms underlying dental, oral, and craniofacial (DOC) conditions and disorders. The ultimate goal is to enable early prevention, diagnoses, and treatments of DOC conditions and disorders on individual basis. Interests in this area include but are not limited to:

- A. Develop advanced assays and reagents that allow robust and scalable throughput to genetically engineer and functionally characterize organisms in craniofacial development and genetics studies.
- B. Develop novel or improved methods and devices that are minimally or non-invasive, cost effective, and sensitive, for early detection of DOC conditions and disorders using imaging, multi-omic, and other state-of-the art technologies and approaches. Methods and devices suitable for Point of Care, at home, and telemedicine uses are encouraged.
- C. Develop methods that are applicable to early treatments (as early as in utero or perinatal, or at a later developmental stage) for human DOC conditions and disorders.

### **Translational Dental, Oral, and Craniofacial Data Science**

Priorities are to 1) maximize the utility of Big Data to accelerate DOC research and 2) better enable evidence-based and data science-driven clinical practices. Interests in this area include but are not limited to:

- A. Develop advanced analytics to retrieve diverse, multi-dimensional data from data repositories, knowledgebases, literature, electronic health/dental/medical/records, and other sources, and infer relations between data elements to inform basic and clinical DOC research. Machine Learning/Deep Learning/Artificial Intelligence (ML/DL/AI) and natural language processing tools are considered highly relevant.
- B. Develop phenotyping, data curation, and data analysis web interfaces for clinicians to support clinical decision making.
- C. Develop devices, including those for Point of Care, at home, and telemedicine uses, for the diagnoses of DOC conditions and disorders. Examples include, but are not limited to, imaging and AI based facile devices.

### **Infectious Diseases and Immunity**

Research relating to the etiology, pathogenesis, prevention, diagnosis and treatment of infectious diseases of the oral cavity is supported by the NIDCR. This includes research on practical ways to effectively use the host immune system to prevent or treat oral infectious diseases and microbial-

induced inflammation. Infectious diseases of the oral cavity include caries, periodontitis, candidiasis, peri-implantitis, pulpitis, and various viral, bacterial, and fungal infections of the oral mucosa and research on the diagnosis and prevention of oral manifestations and malignancies of HIV infection and AIDS. Specific examples of technology development needs include but are not limited to:

- A. Develop ways to overcome or eliminate the risk of oral infections in persons who smoke or chew tobacco, drink alcohol, or are immunosuppressed, have diabetes, are malnourished, or are psychologically stressed.
- B. Explore novel methods or agents to eradicate oral biofilms (dental plaque) on teeth, oral soft tissues, and dental implants without adversely affecting the normal oral flora.
- C. Isolate, synthesize or prepare new antibiotics and antimicrobial agents that can overcome bacterial and fungal resistance to current compounds. Formulate combinatorial drug regimens to attack microbes growing in oral biofilms (dental plaque).
- D. Develop controlled release systems for local delivery of synthetic peptides, recombinant proteins, or other chemical or immunotherapeutic agents to prevent, control, and/or treat oral infectious diseases, or the oral manifestations of HIV infection.
- E. Develop biological response modifiers or other immunological approaches to reduce or eliminate microbial-induced chronic inflammation or the tissue destruction associated with chronic inflammation in the oral cavity.
- F. Develop ways to interfere with microbial colonization and growth through the use of antimicrobial agents and chemotherapy.
- G. Identify and exploit the structural features of oral biofilms for increased therapeutics delivery.
- H. Develop computer programs and apply systems biology approaches to model biologically active peptide regions of oral components that have anti-fungal, anti-bacterial and anti-viral activities.
- I. Develop substitutes of naturally occurring chemicals (phytochemicals) known to have a role in controlling opportunistic infections induced by HIV.
- J. Develop synthetic peptides and recombinant proteins of oral components with anti-fungal, anti-bacterial and anti-viral activities including those against HIV and oral opportunistic pathogens.
- K. Develop oral topical formulations with combined microbicide, analgesic, and anti-inflammatory activities to enhance oral mucosal defenses and prevent and/or control oral infections and lesions in HIV-infected and/or immunosuppressed subjects.
- L. Discover, test, standardize, and validate novel biomarkers present in oral biospecimens for screening and clinical diagnosis of HIV, and oral opportunistic pathogens infections and AIDS malignancies. Apply similar strategies as listed below for oral, oropharyngeal and salivary gland cancers to AIDS malignancies.
- M. Develop the next generation of rapid tests and point of care devices to detect, quantify, screen, and diagnose HIV and oral opportunistic pathogens. Develop novel assays to quantify oral mucosal reservoirs for oral viruses, oral immune responses to viral prophylactic and therapeutic vaccines, and viral changes due to anti-viral treatments.
- N. Develop safe and effective targeted diagnostic and therapeutic technologies in response to endemic and pandemic infections.

### **Oral, Oropharyngeal and Salivary Gland Cancers**

Emphasis is on molecular mechanisms of oral epithelial cell deregulation that lead to oral cancers. Research related to early detection, diagnosis, and prevention, and treatment of oral

cancers is of particular interest. Examples include but are not limited to the following areas:

- A. Develop imaging techniques for the early detection, diagnosis and prognosis of pre-malignant lesions.
- B. Develop effective pharmacological, immunological and radiological modalities for treatment of pre-malignant and malignant lesions in preclinical models.
- C. Develop novel technologies for the genetic and molecular-targeted therapy (e.g. siRNAs, peptide-based therapies) in preclinical models.
- D. Develop genetic animal models of oral cancer premalignancy and oral cancer progression that mimic human oral cancers, including HPV-associated oropharyngeal cancers.
- E. Develop animal models to facilitate the testing of therapeutic and chemopreventive agents for oral cancers.

### **Temporomandibular Disorders and Orofacial Pain**

Emphasis is on research for chronic disabling painful diseases of the oral-craniofacial-dental areas including chronic pain, neuropathies, and diseases of the temporomandibular joint. NIDCR encourages applications that include but are not limited to:

- A. Develop improved methods and technologies for measuring nociceptive, chemosensory, tactile, kinesthetic, or proprioceptive function involving craniofacial structures. Such measures may be useful in screening for deficits, improving diagnosis, or for evaluating responses to orofacial treatments or interventions.
- B. Develop improved biomarkers for neuropathic pain conditions affecting oral-craniofacial tissues or structures.
- C. Develop assays facilitating reliable evaluations of relationships between biological and other risk factors as they relate to onset, and exacerbation of pain and for examining transition from acute pain to chronic pain conditions.
- D. Identify and develop novel pharmacologic or biological agents, and non-pharmacologic methods/approaches, including but not limited to small molecules, peptides, recombinant proteins, nucleic acids, electrical stimulation, and others which could be grouped broadly to electromagnetic induction to modulate mood/nerves, to prevent, control, and/or treat orofacial pain.
- E. Develop animal models to facilitate testing of therapeutic agents for orofacial pain.

### **Saliva, Salivary Diagnostics, and Salivary Gland Diseases**

Emphasis is on salivary gland physiology and pathophysiology and in the repair and restoration of the damaged gland. Examples include but are not limited to:

- A. Develop viral, non-viral and gene therapy-based approaches to address compromised salivary gland function. Develop cell and tissue-based strategies and technologies for restoration of damaged or destroyed salivary gland function.
- B. Develop novel compounds or materials that protect and preserve salivary glands from head and neck cancer irradiation therapy.
- C. Develop non-invasive methods for the determination of efficacy and safety of artificial saliva, sialogogues, and their delivery vehicles used in addressing the diminution or lack of saliva (xerostomia) due to Sjögren's Syndrome or head and neck cancer irradiation therapy.

- D. Develop biomarker-based technologies for the identification of Sjögren's Syndrome using blood or saliva as body fluids.
- E. Identify biomarkers derived from oral fluids that are predictive of the onset, progression and recurrence of oral diseases and conditions, such as periodontal diseases, caries, and oral, oropharyngeal and salivary gland cancers.
- F. Develop immunological strategies and immunotherapy-based approaches for addressing xerostomia from Sjögren's Syndrome.
- G. Improve existing or develop new tools for early detection of salivary gland cancers.

### **Biotechnology, Biomaterials, and Applications for Regeneration and Restoration of Oral, Dental and Craniofacial Tissues**

Emphasis is placed on the development of a broad range of technologies targeted at regeneration and restoration of diseased and injured hard and soft tissues of the oral and craniofacial complex and on translating these applications to the clinic. Tissues of interest include craniofacial and alveolar bone, the periodontal ligament, TMJ bone and cartilage, oral mucosa, facial skeletal muscle, vasculature and nerves. Also of interest are multi-tissue composites and organs, such as vascularized and innervated bone and muscle, salivary gland, tooth, periodontium, bone-periodontal ligament-cementum interface and osteochondral complexes. Specific topics could include but are not limited to:

- A. Develop technologies for design, fabrication, and manufacturing of biomimetic and biocompatible biomaterials and a range of structurally complex scaffolds, including nanomaterials and self-assembling nano-scaffolds, for tissue engineering and regenerative medicine applications. Projects need to include assessments demonstrating the ability of biomaterials and scaffolds to support generation and regeneration of mineralized tissues that replicate the mechanical, physical and biological properties of dentin, enamel, cementum, or bone.
- B. Develop cell-based technologies, including stem cell-based technologies. These include, designing strategies for isolation, purification, differentiation, scaled up production, manufacturing, standardization and quality control of stem and progenitor cells and their differentiated progenies, derivation of efficient and predictable methodologies for cellular reprogramming, and advancing technologies for reconstruction of stem cell niches for augmenting tissue regeneration.
- C. Develop bioreactor systems to facilitate design, fabrication, and manufacturing of soft and hard tissues of dental, oral and craniofacial complex. These bioreactors may be able to mimic biophysical forces, such as mechanical and electrical forces that normally guide tissue morphogenesis *in vivo*. Among other desirable features of the bioreactors are maintenance of tissue construct oxygenation and real-time tissue assessment to encompass metabolites, gene expression, or proteomics evaluation, in addition to morphology and spatial imaging by labeling capabilities.
- D. Develop improved dental composite materials and bonding agents, including biomimetic and self-healing materials and adhesive sealants. These include but are not limited to materials to replace Bis-GMA resin-based systems that are suitable for restoring crowns of posterior teeth and exposed roots of the teeth. Any novel dental composite restorative components or systems must include assessments in a physiologically relevant test system that mimics microbial and physicochemical conditions found in the oral cavity.
- E. Develop methods, materials, and devices for orthodontic, prosthetic, periodontic, endodontic and craniofacial applications including those that can be used for craniofacial bone distraction, reconstruction, hard and soft craniofacial tissue healing and regeneration,



and scarless craniofacial tissue repair.

- F. Develop miniaturized artificial tissue and organ mimics/tissue chips and organoids that can be adapted to high-throughput formats for a broad range of applications, such as analysis of biomaterial and tissue function, drug efficacy and toxicology assays, biocompatibility assays, genetic screening and elucidating mechanisms of dental, oral and craniofacial development and disease.
- G. Develop mathematical, computational, and bioinformatics approaches for modeling oral and craniofacial tissues and organ function and physiology to address needs of systems biology, synthetic biology, and single cell analysis. Develop new approaches for utilizing novel biomolecules, including growth factors, cytokines, small molecules, siRNAs, and others for counteracting diseases and injuries of oral and craniofacial tissues and promoting their healing and regeneration.
- H. Develop new approaches to study molecular or cellular interactions between hard and soft tissues such as between the nervous system and mineralized tissues. Approaches can include development of new technologies or application of existing technologies that are newly applied to the dental and craniofacial field.
- I. Develop advanced viral and non-viral based biomolecule delivery approaches, including nanotechnology-based technologies that can precisely deliver and release therapeutic proteins, nucleic acids, small molecules, or combinations thereof with predictable temporal kinetics to target specific tissue sites.
- J. Develop imaging diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for various applications, including but not limited to dental caries, cracked teeth, pulp vitality, bone quality, and periodontal disease.
- K. Develop imaging diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for various applications, including but not limited to dental caries, cracked teeth, pulp vitality, bone quality, and periodontal disease.
- L. Develop safe and effective biosensors for noninvasive, dynamic real-time monitoring of physiological processes in the human body using the oral cavity as the sensing site. These biosensors will be able to assess health and disease states and receive feedback from body fluids and clinical compounds that are found in or pass through the oral cavity and in certain cases, will be able to communicate these outputs wirelessly and remotely.
- M. Develop safe and effective biosensors, monitoring devices and systems, data driven and computer science tools for automated detection, diagnosis and treatment of dental, oral and craniofacial disease.
- N. Develop effective multimodal breakthrough technologies for real-time detection of proven disease biomarkers, viruses and/or pathogens with high sensitivity and specificity that integrate detection technologies, such as optical spectroscopy, electrical impedance, radio frequency, acoustic, and immunosensing, with multiplexing capability.

## **Preclinical Research**

- A. Preclinical research and development activities for dental and craniofacial technologies including the translation of innovations devices, drugs, biologic and combination products (reconstructive materials, regenerative products, pharmaceuticals, therapeutics, vaccines, digital health technologies) that require review and approval by the FDA as a regulated product before commercial distribution.

## **Biomedical Clinical Research**

Emphasis is on development of methods, drugs and materials to diagnose or treat oral and craniofacial diseases and conditions. Areas of interest include but are not limited to projects that:

- A. Develop improved methods to detect and predict progression of dental caries, periodontal disease, reversible and irreversible pulpitis.
- B. Develop improved methods or materials to prevent dental, oral, and craniofacial diseases or conditions.
- C. Develop new or improved methods or materials to enhance oral and craniofacial surgery. This would include both intraoral and extra-oral surgery.
- D. Develop improved methods or materials to mechanically and/or biologically repair or treat tooth structure damaged by dental caries or periodontal disease.
- E. Develop, customize, and validate data-driven technologies coupled with automated high throughput tools that accelerate development and regulatory evaluation of novel biomaterials.
- F. Develop improved appliances to aid suckling and improve speech production by newborn infants with cleft palate and cleft lip.
- G. Develop safe and efficacious methods to diagnose caries, pulp vitality and / or periodontal diseases utilizing non-ionizing radiation.
- H. Develop technologies for local delivery of drugs to treat oral and craniofacial diseases or disorders.
- I. Develop novel non-opioid pharmacological medications for management of acute dental pain.
- J. Develop safe and efficacious methods or medications to manage complications of head and neck cancer treatment.
- K. Develop tools for implementation of precision medicine in the oral cavity.
- L. Develop methods and tools to detect soft tissue pathologies in the oral cavity.
- M. Develop oral devices and materials for monitoring local and systemic conditions.

## **Behavioral Clinical Research**

Provides support for the development of evidence-based products related to behavioral and social aspects of oral health, oral health prevention or treatment interventions, and other patient-oriented aspects of oral health. This includes support for clinical trials and patient-oriented research to establish safety and initial efficacy of products. NIDCR is especially interested in applications that significantly improve oral health by 1) being broadly applicable to many populations, 2) contributing to meaningful oral health improvements for a specific population, 3) expediting translation of research findings into oral health improvements, and/or 4) equipping oral health care providers, educators or researchers with tools to improve public oral health.

Examples of studies of interest include, but are not limited to, the following:

- A. Develop and test the effectiveness of innovative teaching or educational tools or curricula to inform oral health professionals and dental students regarding the role of genetics and genomics, including the oral microbiome, in oral diseases, conditions and oral health care; and/or oral cancer prevention and early detection.
- B. Develop and test digital health, connected technologies, and approaches to improve time-sampled monitoring of behavioral adherence with preventive, condition management, or therapeutic regimens specifically relevant to oral diseases/conditions. Such devices or

methods could be utilized in a variety of settings, including naturalistic settings, within clinical trials, within oral health care delivery systems, etc.

- C. Develop and test novel compliance and survey measures or tools to identify the underlying causes of insufficient preventive dentistry for specific underserved populations.
- D. Develop and test for safety, efficacy, and/or effectiveness of measures or materials for diagnosing, preventing, or treating oral, dental, and craniofacial conditions and disorders.
- E. Develop or adapt for use in new populations or settings: Novel measures or methods for identifying individual, family, group, or other processes that explain oral health behavior; oral health interventions utilizing technology to improve efficiency of delivery (e.g., management of chronic pain related to temporomandibular joint disorders, etc.); interventions addressing health behaviors highly associated with oral health (e.g., tobacco, alcohol, and other drug use; management of diabetes, HIV infection, or other chronic illnesses; etc.).
- F. Develop and test innovative methods for facilitating collaborations, referrals, and/or ongoing follow-ups between oral health professionals and other health care professionals across primary and specialty practices.
- G. Develop technologies or modules beyond existing web-based platforms to improve preventive oral health hygiene for children and adolescents (e.g., social marketing via app- and web-based interaction, virtual reality “worlds”, “massively multiplayer online games”, etc.).
- H. Develop and test web-based training or other innovative approaches for oral health care professionals to accelerate accurate translation of new knowledge regarding oral diseases and their effective prevention or treatment into clinical or public health practice.

### **Contact Information**

For additional information on research topics,  
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# NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

## **Mission**

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life. For additional information about areas of interest to the NIDDK, please visit our home page at <http://www.niddk.nih.gov>. See our SBIR/STTR page at <https://www.niddk.nih.gov/research-funding/research-programs/small-business>.

Please also find the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Strategic Plan for Research, published in December 2021, at <https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/niddk-strategic-plan-for-research>.

## **Budget Guidance**

For budgetary, administrative, or programmatic reasons, the NIDDK may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found in the "Award Budget" section of the current Omnibus Solicitations. With appropriate justification from the applicant, the NIDDK may consider budgets that exceed these amounts to support research that aligns with an approved waiver topic (see [SBA-Approved Waiver Topics](#)).

The NIDDK generally considers:

- Phase I budgets up to \$350,000 total costs or project periods up to 2 years.
- Phase II applications up to \$2,200,000 total costs or project periods up to 3 years (Phase II budgets generally should not exceed \$1,100,000 total costs in any year).
- Phase IIB (see below) applications up to \$3,000,000 total costs or project periods up to 3 years (Phase IIB budgets generally should not exceed \$1,100,000 total costs in any year).

*Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff with a draft of their Specific Aims page before submitting an application.*

The NIDDK also participates in the SBIR/STTR Commercialization Readiness Pilot (CRP) Program. Applicants should review the Award Budget section of relevant Notices of Funding Opportunities. For Phase II awardees, especially those developing products that require clinical evaluation or approval by a Federal regulatory agency, the NIDDK strongly encourages potential applicants to apply to NIDDK's Phase IIB program.

## **Specific SBIR and STTR Program Information**

NIDDK will accept clinical trials in most of the areas within the mission of the NIDDK. NIDDK does not support clinical trials in hematologic diseases.

## **Final Progress Reports**

As detailed in [NOT-OD-17-085](#), the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NIDDK is interested in tracking the progress of the small business concerns it funds and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but also their growth as a small business concern towards independence from the SBIR/STTR program.

## **Additional Programs and Services for NIDDK SBIR/STTR Awardees**

The NIDDK encourages awardees to apply to participate in programs NIH offers to support the development of their products (<https://seed.nih.gov/support-for-small-businesses>). The NIDDK may offer additional programs throughout the year, and awardees are encouraged to keep their contact information current so that they receive announcements regarding these programs.

## **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIDDK will accept Phase IIB SBIR/STTR Competing Renewal grant applications (only) from NIDDK-supported Phase II awardees that propose to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, and 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Such products include, but are not limited to biological products, devices, drugs, medical implants, etc. related to the mission of the NIDDK. These awards are intended to support completion of research needed for an Investigational New Drug (IND) application or Investigational Device Exemption (IDE). Applicants must provide evidence that they have consulted formally with the U.S. the Food and Drug Administration (FDA) concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes. Applicants should describe these consultations and the outcomes in the Progress Report section of the Research Strategy and provide FDA correspondence or meeting minutes as part of Just-in-Time procedures.

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities.

- Completion of studies as required by the FDA for an IND or Radioactive Drug Research Committee (RDRC) application.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Clinical studies in support of an application for clearance or approval by the FDA. See the table below and review NIDDK's Policies for Clinical Researchers (<https://www.nidddk.nih.gov/research-funding/human-subjects-research/policies-clinical-researchers>) when considering an application involving human subjects.

The NIDDK also participates in the SBIR/STTR Commercialization Readiness Pilot (CRP) Program. Please review CRP NOFOs for NIDDK’s participation. For Phase II awardees, especially those developing products that require clinical evaluation or approval by a Federal regulatory agency, the NIDDK strongly encourages potential applicants to apply to NIDDK’s Phase IIB program.

**Clinical Trials**

Does NIDDK accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	The NIDDK accepts SBIR, but not STTR applications with NIH-defined clinical trials.
Does NIDDK accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does NIDDK support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<p>Small businesses are eligible to apply for several non-SBIR/STTR funding opportunities. Comprehensive information on Human Subjects Research at NIDDK can be found here: <a href="https://www.niddk.nih.gov/research-funding/human-subjects-research">https://www.niddk.nih.gov/research-funding/human-subjects-research</a></p> <p>The NIDDK has a R01 funding opportunity for pilot &amp; feasibility clinical trials and accepts <b>low-risk</b> clinical trials within the mission of the NIDDK through the parent NIH NOFOs for clinical trials.</p> <p>For <b>high-risk</b> clinical studies (see NOT-DK-20-051: <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-DK-20-051.html">https://grants.nih.gov/grants/guide/notice-files/NOT-DK-20-051.html</a>) that involve more than one research centers, NIDDK uses a two-part process that usually requires use of a U34 planning grant followed by a separate application for the clinical trial or study (U01). <b>Potential applicants are strongly encouraged to contact NIDDK staff</b> to discuss their proposed study and determine the most appropriate mechanism for submitting their application.</p> <p>Clinical Trials Allowed and Optional funding opportunities to which NIDDK is subscribed can be found on NIDDK’s Current Funding Opportunities page: <a href="https://www.niddk.nih.gov/research-funding/current-opportunities">https://www.niddk.nih.gov/research-funding/current-opportunities</a>.</p>

**Research Topics**

**Diabetes, Endocrinology and Metabolic Diseases**

The Division of Diabetes, Endocrinology and Metabolic Diseases supports SBIR/STTR projects in the areas of type 1 and type 2 diabetes, endocrine disorders, and neuroendocrinology. High priority topic areas are listed below:

## **II. Sensors, Hormone Replacement, Delivery Devices, and Other Technologies for Diabetes Treatment:**

- A. Novel accurate, reliable, and user-friendly continuous monitoring sensor technologies relevant to diabetes treatment and monitoring. Preferably, these sensors should have long functional life, and for glucose sensing be accurate at all glycemic ranges, particularly at concentrations below 54 mg/dl.
- B. Use of Artificial Intelligence, Machine Learning (AI/ML) tools to enable fully automated closed loop pancreatic hormone delivery systems in response to multi-analyte physiological input.
- C. Novel insulin and glucagon formulations showing improved kinetics and stability.
- D. Telemedicine/remote monitoring approaches that can be incorporated as components/and or adjuvants of closed loop systems for better diabetes self-management.
- E. Technologies that may promote and facilitate adherence/compliance by users of diabetes monitoring and control devices.
- F. More reliable and efficient biocompatible infusion sets for automated hormone delivery and improved kinetics.
- G. New implantable and easy to replace technologies that may mimic the beneficial effect of gastric bypass/bariatric surgery for the treatment of diabetes without the need of a major invasive surgical procedure.

## **III. Diabetic Wound Healing and Diabetic Neuropathy:**

- A. Drugs, biologic therapies, and novel delivery systems that accelerate healing of diabetic foot ulcers and prevent recurrences.
- B. Off-loading devices that improve patient acceptability and adherence.
- C. Diagnostic and predictive biomarkers, including improved outcome measures, for diabetic foot ulcers that can be used to diagnose biofilms, predict healing, select treatment strategies, or determine risk of primary or secondary occurrence of foot ulcers. The biomarkers may use biosamples, images or sensors.
- D. Educational approaches and new technologies that increase adherence to preventative measures for diabetic foot ulcers in high-risk patients or increase adherence to off-loading and other recommended treatment regimens for diabetic foot ulcers.
- E. Disease-modifying therapies for the prevention and treatment of diabetic neuropathy.
- F. Sensors, algorithms, and patient interfaces that can provide feedback to diabetic individuals with insensate feet to prevent diabetic foot ulcers.
- G. Biomarkers to monitor disease progression and response to therapy for diabetic neuropathy, including peripheral sensory, autonomic, and painful diabetic neuropathy.

#### **IV. Immune Modulation and Cell Replacement Therapies:**

- A. Development of immunomodulation/tolerance strategies, including cell-based, to prevent, revert or slow progression of type 1 diabetes.
- B. Development and optimization of engineered islet cell replacement sources with improved transplant graft attributes, including but not exclusive to: graft function durability under transplantation and metabolic stress; graft survival with lowered or no systemic immunosuppression and non-invasive quantitative monitoring of graft mass.
- C. Novel biomimetic and immuno-engineering strategies for the development of immune evasive cells/islets and biomaterials/devices for successful long-term engraftment with no need of systemic immunosuppression.
- D. Development of reproducible methods that improve yield/viability/function of islets/insulin producing cells and allow their ex-vivo expansion for transplantation.

#### **V. Prediction, Screening, Diagnostics, and Monitoring:**

- A. Development of methodologies, products, or biomarkers useful for predicting, preventing or delaying progression of pre-diabetes or diabetes, including tests for identifying patients at risk, and methods of monitoring disease progression.
- B. Validated tests for autoantibody detection, auto-reactive T-cells and other immune/metabolic parameters for type 1 diabetes early diagnosis and monitoring. Improvements could include higher throughput - point of care technologies (reliable, accurate, cost-effective, highly sensitive, and standardized with rapid turnaround time).
- C. Multiplexed assays for peptides and proteins that are used as biomarkers in diabetes and metabolic diseases (e.g., insulin, pro-insulin, glucagon, c-peptide, HbA1c..etc).
- D. Development of non-invasive technologies such as imaging for the in vivo measurement/evaluation of pancreatic islet's cell mass, function and inflammation.
- E. Artificial Intelligence, Machine Learning, and Deep Learning driven methods and technologies that may optimize prediction, diagnosis, monitoring and treatment of diabetes, endocrine and metabolic disorders.

#### **VI. Pre-Clinical Research and Disease Modeling:**

- A. Development and optimization of microphysiological/organ on chip platforms in the application of pre-clinical testing and/or modeling of physiological and pathophysiological aspects of diabetes, endocrine and metabolic disorders.
- B. Development of methods utilizing replenishable cell sources, that generate functional islet like cells/tissues that can be successfully tested in microphysiological systems and/or *in vivo* models of the disease.
- C. Development and testing of *in silico*/simulation models with predictive capability to complement and/or replace *in vitro* and *in vivo* pre-clinical testing.

#### **VII. Tools for Measuring Peripheral Neurotransmitters and Neuromodulation:**

- A. Devices that modulate or control the hepatic or pancreatic branches of the vagus nerve with the aim of relieving diabetes or other metabolic disorders. Projects concerned with the liver should be focused on the regulation of glucose or lipid



metabolism. Technologies would include closed- or open-loop neural stimulators of sensory or motor nerves originating from or terminating in the endocrine pancreas or liver.

- B. Tools that provide high spatio-temporal resolution of neurotransmitter release in the endocrine pancreas or liver.
- C. Tools that measure autonomic activity in the liver, endocrine pancreas, or adipose tissue in animal models or humans.

## **Digestive Diseases and Nutrition**

The Division of Digestive Diseases and Nutrition supports research in diseases and disorders of the digestive tract; esophagus, stomach, intestine, colon, anorectum, pancreas, liver, gallbladder, and biliary tract; as well as research in nutrition and obesity. Innovative investigator-initiated projects that are not mentioned below are also encouraged. Examples of areas that may be of interest to small businesses include, but are not limited to:

### **I. Gastrointestinal**

- A. Development of new diagnostic techniques and tests, including non-invasive tests and imaging for detecting Barrett's esophagus, GERD, and other intestinal disorders.
- B. Development of agents and techniques to measure, diagnose, stimulate regeneration of enteric neurons, and treat motility disorders.
- C. Development of novel therapies to modulate/enhance GI lymphatic function for the treatment of GI pathologies.
- D. Development of gut-derived biomarkers of neurodegenerative brain disease.
- E. Development of approaches to simultaneously interrogate or modulate the central nervous system (CNS) and the gastrointestinal system.
- F. Development and validation of neurotechnologies that improve the association of symptoms, pathophysiology, and function for gastrointestinal disorders.
- G. Development of novel proteomic or metabolomic technologies designed to study digestive diseases and their complications.
- H. Development of assays and screening methods for detection of biomarkers for diagnosis, grading and staging digestive diseases.
- I. Development of Live Biotherapeutic Products (LBPs), such as probiotic organisms for the prevention or treatment of gastrointestinal conditions, or to enhance the nutritional properties of dietary components. These LBPs would not include vaccines, oncolytic bacteria, or gene therapy agents.

### **II. Liver**

- A. Development of novel antifibrotic therapies for chronic progressive liver diseases.
- B. Development of quantitative tests of hepatic "reserve" for assessment of therapeutic intervention, transplantation, or surgical risk in patients with liver disease.
- C. Development of point-of-care, serologic, and rapid tests for rapid diagnosis, treatment

requirements and genotyping of hepatitis.

- D. Development of rapid, reliable, and inexpensive tests for genetic screening and risk markers important in liver disease.
- E. Development of sensitive and reliable non-invasive techniques to detect and monitor liver fibrosis and other chronic liver diseases and the associated complications.
- F. Creation of bio-artificial organs for temporary hepatic support in patients with acute liver failure.

### **III. Pancreas**

- A. Development of and validation of therapeutic interventions for treatment of pancreatitis and its complications.
- B. Development of more accurate, non-invasive approaches to the diagnosis of chronic pancreatitis by functional, radiologic, endoscopic, or pathologic/cytologic means.

### **IV. Nutrition/Obesity**

- A. Development of novel methods and tools to accurately evaluate nutritional status, physical activity, and energy expenditure.
- B. Development of non- or minimally invasive technologies that allow access and/or delivery to discrete regions of the digestive tract.
- C. Development of novel breath, urine, or blood tests to accurately measure dietary intake.
- D. Development of non-invasive neurotechnologies to stimulate and/or modulate hormone/peptide release from the gastrointestinal system for the treatment of metabolic disorders such as obesity.

## **Kidney, Urologic and Hematologic Diseases**

The Division of Kidney, Urologic, and Hematologic Diseases provides research funding and support for basic, translational, and clinical research studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. Projects may include development of tools to improve understanding of the physiology, pathophysiology, and diseases of the kidney, urinary tract, and blood and blood forming systems, or to develop rational diagnostics, treatments, and prevention strategies for these diseases. Projects may be to develop tools/technologies to support clinical care, population health and/or pragmatic research to improve health outcomes in populations with kidney diseases and/or urologic conditions. Projects to develop tools or technologies to address health disparities or promote health equity are encouraged. NIDDK encourages research that takes a holistic perspective of human health by considering biological, behavioral, and social contributors to the scientific exploration, prevention, and management of these diseases/conditions. Development of -omics, bioinformatics, and multi-scale technologies for the study of these systems, especially where these systems interact, is also encouraged. Research opportunities that may be of interest to small businesses include, but are not limited to:

### **I. KIDNEY DISEASES**

Areas of research include chronic kidney disease, end-stage renal disease, diabetic kidney disease, polycystic kidney disease, hypertensive kidney injury, acute kidney injury, kidney

donation (delayed graft function and chronic rejection), congenital kidney disorders, glomerular and tubulointerstitial diseases, IgA nephropathy, hemolytic uremic syndrome, fluid and electrolyte disorders, kidney repair and regeneration, and normal and abnormal kidney development and physiology.

### ***Dialysis, Devices and Medical Technologies***

- A. Development of innovative forms of renal dialysis which improve efficiency, have lower associated morbidity (e.g., tissue engineered artificial kidneys, implantable or wearable dialyzers), reduce side effects and constraints of dialysis treatment, and/or improve access, experience, and quality of life.
- B. Development of functional nephrons for transplantation.
- C. Development of pharmacological agents, devices, techniques, or diagnostics that enhance maturation and longevity of a vascular access.
- D. Development of dialysis membrane technologies with enhanced biocompatibility and anti-fouling properties.
- E. Development of a means to provide continuous anticoagulation to permit renal replacement therapy.
- F. Development of reliable, non-invasive, wearable or online monitoring systems for real-time assessment and adjustment of treatment parameters such as blood volume, access flow, and urea clearance.
- G. Development of hemodialysis or peritoneal dialysis catheters using improved biomaterials, which reduce catheter-related infections, the foreign body response, biofouling, and biofilm formation.
- H. Development of novel methods to generate dialysate for hemodialysis or peritoneal dialysis.
- I. Development of devices or techniques to enhance the long-term success of kidney transplantation (e.g., techniques for repairing kidneys or for kidney storage and preservation).
- J. Development of technologies to improve kidney biopsies (i.e., to improve safety or tissue acquisition).

### ***Health Information Technologies***

- K. Development of health information technologies or mobile technologies that enhance delivery of care, population health management, health equity, and/or research for patients with kidney diseases.
- L. Development of applications or application programming interfaces that use health data standards (e.g., Fast Healthcare Interoperability Resources [FHIR], clinical terminologies) to improve accessibility, accuracy, and/or completeness of real-world health, behavioral, and societal/contextual data for research and care of individuals with kidney diseases.
- M. Development of technologies to engage patients with kidney diseases in their care or to support interaction with caregivers.
- N. Development of innovative technologies or platforms to facilitate kidney research training and education, which could include software or simulation tools.

### ***Diagnostics and Imaging***

- O. Development of clinical assays that enable biopsychosocial precision medicine approaches to treating kidney diseases.
- P. Development of technologies that use artificial intelligence/machine learning (AI/ML) or other advanced statistical approaches to integrate disparate data types to inform diagnosis of kidney diseases. AI/ML approaches should leverage data from diverse populations and apply equity considerations to ensure resulting models do not further embed structural racism or discrimination.
- Q. Development of platforms for pre-analytical preparation, imaging, and automated analysis of kidney tissue.
- R. Development of non- or minimally invasive methods for evaluating kidney functions, including in individuals with congenital genitourinary conditions.
  1. Reliable, non-invasive, non-radioactive methods of measuring glomerular filtration rate (GFR) or tubular functions.
  2. Translation of biomarkers of acute kidney injury or chronic kidney disease with clinical utility into commercial assays.
  3. Translation of biomarkers for early detection of kidney diseases or prediction of kidney disease progression, recovery, or drug response.
- S. Development of improved renal imaging techniques, differential renal function assessment, diagnostic assessment of non-malignant kidney diseases, or measurement of perinatal nephron endowment.
- T. Development of technology to improve collection of real-time data (e.g., biomarkers, diet, physical activity, patient reported outcomes, vital signs, patient experience of kidney or urologic disease or its treatment, social or environmental factors which affect the development or progression of kidney disease), patient outcomes, and adherence for clinical studies.
- U. Development of imaging or molecular analysis technologies to enhance information extraction from renal biopsies and development of antibodies or other probes for unique cell types of the kidney.

### ***Therapeutics Discovery and Development***

- V. Lead optimization and preclinical development of pharmacological agents that might be used to intervene in acute or chronic renal disorders and in disorders of renal hemodynamics, blood pressure, electrolyte metabolism, and extracellular volume regulation.
- W. Development of drugs or biologics designed to specifically target kidney cell types.
- X. Development of drugs or biologics to stimulate productive kidney repair or regeneration.
- Y. Development of technologies to enhance the validation of kidney disease targets or to screen compounds for efficacy or toxicity (e.g., kidney organoids or tissue chips, more relevant animal models of acute kidney injury).
- Z. Development of data and cell banks (e.g., of diabetic kidney disease families and polycystic kidney disease families) for use by the research community.
- AA. Development of preventative measures for acute kidney injury (e.g., during coronary artery bypass grafting, sepsis, or treatment with nephrotoxic agents).

## II. UROLOGIC DISEASES

Areas of research include benign prostatic hyperplasia, lower urinary tract symptoms (LUTS) including urinary incontinence, urinary tract infections, urinary stone disease, erectile dysfunction, urologic chronic pelvic pain syndromes (including interstitial cystitis and chronic prostatitis), congenital urologic disorders, repair and regeneration of lower urinary tract organs, normal and abnormal lower urinary tract development, and physiology of the urinary system and male genital organs (excluding applications targeting male fertility).

### ***Diagnostics and Imaging***

- A. Translation of blood or urine biomarkers in the lower urinary tract or other urologic disorders into commercial assays with clinical utility.
- B. Development of non-invasive or minimally invasive methods to diagnose bladder inflammation or changes in the urothelium that are not of a cancerous origin.
- C. Development of new technologies for rapid clinical diagnosis and characterization of urinary tract infection (UTI).
- D. Development of new technologies or methods with reduced radiation dose for evaluating vesico-ureteral reflux in children and infants.
- E. Development of diagnostic modes to clinically and non-invasively or minimal-invasively measure bladder outlet obstruction before and after surgical or pharmaceutical intervention.
- F. Development of objective diagnostic devices or methods for the assessment of urinary storage and voiding disorders, including stress, urge, and mixed incontinence, in both adults and children.
- G. Development of wireless and non-invasive or minimally invasive measurement technologies for real-time assessment of lower urinary tract function, which can include neuro- pharmacological/neuro-physiological urodynamics.
- H. Development of radiation-free and accurate imaging technologies for urinary stone disease.
- I. Development of technologies that use artificial intelligence/machine learning (AI/ML) to integrate disparate data types to inform diagnosis of urologic diseases. AI/ML approaches should leverage data from diverse populations and apply equity considerations to ensure resulting models do not further embed structural racism or discrimination.
- J. Development of platforms for pre-analytical preparation, imaging, and automated analysis of genitourinary tissues.

### ***Drug and Device (Therapeutic) Interventions***

- K. Lead optimization and preclinical development of pharmacological agents for treatment or prevention of urinary stone disease, urological chronic pelvic pain syndromes, urinary tract infections, or other urologic diseases or conditions within NIDDK's mission.
- L. Development of novel neuromodulation devices, which restore function or mitigate pain conditions of the lower urinary tract.
- M. Development of urinary catheters which reduce the incidence of infection in the

urinary tract and decrease urethral and bladder inflammation.

- N. Development of technologies for treatment of bladder outlet obstruction.
- O. Development of bioengineered materials or structures, including cell-laden structures, for the repair or regeneration of genitourinary organs.

### ***Health Information Technologies***

- P. Development of health information technologies or mobile technologies that enhance delivery of care, population health management, health equity, and/or research for patients with urologic diseases or conditions.
- Q. Development of applications or application programming interfaces that use health data standards (e.g., Fast Healthcare Interoperability Resources [FHIR], clinical terminologies) to improve accessibility, accuracy, and/or completeness of real-world health, behavioral, or social data for research and care of individuals with urologic diseases or conditions.
- R. Development of technologies to engage patients with urologic diseases or conditions in their care or to support interaction with caregivers.
- S. Development of innovative technologies or platforms to facilitate urology research training and education, which could include software or simulation tools.

### ***Research Tools***

- T. Development of tools for elucidating the role of urinary or gut microbiome in urinary stone disease or other urologic diseases or conditions within NIDDK's mission.
- U. Development of novel models of benign prostatic hyperplasia.
- V. Development of technology to improve collection of real-time data (e.g., biomarkers, diet, physical activity, vital signs, psychological parameters, and social or environmental factors), patient-reported outcomes, and adherence for clinical studies (e.g., studies of gene-environment interactions in the manifestation of urologic diseases).

## **III. HEMATOLOGIC DISEASES**

The NIDDK hematology research program focuses on understanding basic cellular and molecular mechanisms that underlie the production and function of blood cells in health and disease. The program emphasizes translational applications of new insights and knowledge gained from basic research in these areas toward the development of novel or improved approaches for the diagnosis, stratification, and treatment of hematologic diseases. This includes the development of disease biomarkers, gene targeted therapies, or hematopoietic stem cell transplantation for acquired and heritable blood diseases (e.g., hemoglobinopathies, such as sickle cell disease or thalassemia; hemochromatosis, iron overload, porphyrias, amyloidosis, iron deficiency anemia, and cytopenias resulting from bone marrow failure disorders, congenital dyserythropoietic anemias, Schwachman-Diamond syndrome, myelodysplastic syndrome, neutropenias, myelofibrosis, essential thrombocythemia, or polycythemia vera), and the measurement and chelation of tissue iron in iron overload disorders. The NIDDK hematology research program provides resources for basic and preclinical development efforts leading up to IND or IDE submissions but does not fund clinical trials. The program has a particular focus on myeloid lineage and hematopoietic stem

cells, including the effects of aging on hematopoiesis.

### ***Drug Discovery and Development***

- A. Establishment of robust in vitro or animal models of benign hematologic diseases for drug discovery or development.
- B. Development of therapeutics that target elements of hematopoietic stem cell niches (e.g., stromal cells, osteoblasts, endothelium, macrophages, pericytes, nerve cells).
- C. Development of novel bone marrow conditioning regimens that promote hematopoietic stem cell homing, engraftment, and hematopoiesis.
- D. Development of therapeutics that modulate blood cell production from hematopoietic stem cells and progenitors based upon understanding of physical and chemical regulatory pathways.
- E. Development of therapeutics that modulate metabolism, storage, and transport of iron or heme.

### ***Cell Therapies***

- F. Development of equipment, chemically defined reagents, and methods for high volume ex vivo expansion, isolation, and/or differentiation of highly purified human hematopoietic stem and progenitor cells.
- G. Development of equipment, chemically defined reagents, and methods for selective removal or destruction of diseased human hematopoietic stem and progenitor cells (e.g., in myelodysplastic syndrome, MDS). Treatment of malignant clones and blood cancers are not within the scope of the NIDDK Hematology mission.
- H. Development of therapeutics that induce fetal hemoglobin synthesis by chemical means, genome editing, or other means.
- I. Development of therapeutics that target blood cell membrane structure.

### ***Diagnostics and Imaging, Medical Technologies, and Research Tools***

- J. Development and validation of sensitive, specific, reproducible, quantitative, and clinically applicable assays for measuring levels or expression of iron regulatory molecules or for measuring misfolded or aggregate amyloid proteins such as amyloid A transthyretin or immunoglobulin light chain in blood.
- K. Development of technologies to track, purify, monitor or assay single-cells in vivo or in vitro.
- L. Development of non-invasive systems for monitoring circulating blood cells, blood chemistry or blood cell production.
- M. Development of imaging technology for the non-invasive measurement of bone marrow cellularity, fibrosis, and function.
- N. Development of imaging technology for the non-invasive measurement of tissue iron loading and distribution.
- O. Development of technologies to understand the roles of mitochondria in non-malignant hematologic diseases.

- P. Development of technologies that use artificial intelligence/machine learning (AI/ML) to integrate disparate data types (e.g., histomorphology, karyotyping, next generation sequencing, immunophenotyping, and flow cytometry) to inform diagnosis of non-malignant hematologic diseases. AI/ML approaches should leverage data from diverse populations and apply equity considerations to ensure resulting models do not further embed structural racism or discrimination.
- Q. Development of platforms for pre-analytical preparation, imaging, and automated analysis of the bone marrow.
- R. Development of innovative technologies or platforms to facilitate hematology research training and education, which could include software or simulation tools.

### **Contact Information**

For additional information on research topics, contact:

#### **DIABETIC TECHNOLOGY, TYPE 1 DIABETES AND ENDOCRINE DISEASES**

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#### **DIABETIC WOUND HEALING AND TYPE 2 DIABETES**

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#### **NEUROMODULATION, DIABETIC NEUROPATHY, AND TYPE 2 DIABETES DRUG DISCOVERY**

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#### **GASTROINTESTINAL, OBESITY, AND NUTRITION DISORDERS AND DISEASES**

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#### **LIVER, PANCREATIC, AND NEUROBIOLOGICAL DISORDERS AND DISEASES**

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**KIDNEY, UROLOGIC AND HEMATOLOGIC DISEASES**

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For administrative and business management questions,

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# NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

## **Mission**

The mission of the National Institute of Environmental Health Sciences [www.niehs.nih.gov](http://www.niehs.nih.gov) is to discover how the environment affects people in order to promote healthier lives, with a vision of providing global leadership for innovative research that improves public health by preventing disease and disability. NIEHS achieves its mission and vision through a multidisciplinary biomedical research program, prevention and intervention efforts, and a communication strategy that encompasses training, education, technology transfer, and community outreach.

## **Budget Guidance**

For all NIEHS research interest topic areas other than Hazardous Substances Remediation and Site Characterization SBIR Program included in this PHS 2024 Omnibus SBIR/STTR Solicitation, NIEHS will accept SBIR/STTR application total funding support (direct costs, indirect costs, and fee) requests up to \$306,872 for Phase I and \$2,045,816 for Phase II. NIEHS will not fund applications at budget levels exceeding these hard cap budget guidelines, except through specific RFAs. For budgetary, administrative, or programmatic reasons, NIEHS may decide not to fund an application or may decrease the length of an award and/or the budget. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project, and the budget request must be well justified. The Hazardous Substances Remediation and Site Characterization SBIR Program has different limits on budget requests for both Phase I and Phase II, check under that topic below for details.

NIEHS will consider well justified Technical and Business Assistance (TABAs) costs up to the limits specified on the [NIH SEED website](#). These costs can be requested in addition to the Phase I and II limits indicated above.

## **Specific SBIR and STTR Program Information**

For additional information about NIEHS's Small Business Programs, please visit [Small Business Innovation Research & Small Business Technology Transfer Grants \(SBIR/STTR, R41, R42, R43, R44\) \(nih.gov\)](#). **NIEHS DOES NOT Fund technologies for the detection and remediation of pathogens in the environment.**

## **Final Progress Reports**

As detailed in [NOT-OD-17-085](#), the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NIEHS is interested in tracking the progress of the small business concerns it funds and the products they develop. It is expected that small businesses who have received previous SBIR/STTR grants have had success in commercializing their previously supported technologies. Small businesses that are primarily interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR/STTR program. Funding priority will be given to those small business concerns that demonstrate their ability to develop and commercialize products.

## **Specific Funding Opportunities and Programs**

In addition to this omnibus program announcement, the NIEHS releases targeted SBIR/STTR Notices of Funding Opportunities (NOFOs); sign up for the listserv ([Subscribe or Unsubscribe to the SBIR-NIEHS List \(nih.gov\)](#)) to be notified of NOFOs.

## **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIEHS does not intend to support any new Phase II B grants in this funding period. NIEHS currently participates in [PAR-23-219](#); SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development (SB1, Clinical Trial Not Allowed).

### **Clinical Trials**

Does NIEHS accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NIEHS accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does NIEHS support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	For non-SBIR/STTR clinical trials funding mechanisms for which small businesses are eligible, please visit the <a href="https://www.niehs.nih.gov/funding/grants/announcements/request/index.cfm">https://www.niehs.nih.gov/funding/grants/announcements/request/index.cfm</a> .

### **Research Topics**

#### **NIEHS Non-Clinical Trials Topics:**

##### **Exposure Assessment Tools**

The NIEHS Exposure Biology and the Exposome Program supports technologies to better understand how a person's environment contributes to their health. Sensor technologies, computational approaches, improved biomarkers, and biomonitoring capabilities, are needed to measure, analyze, and predict a wide range of internal and external exposures and health outcomes across diverse geographic populations. These tools should be designed fit-for-purpose in collaboration with the stakeholders (*e.g.*, community engagement programs, citizen scientists, disaster response personnel, epidemiologists, or clinical researchers).

Examples include:

##### **Sensors and Other Exposure Assessment Tools**

- Technologies and methodologies to assess personal exposure to specific or combined air pollutants in population studies, including wearable monitors and sensor networks.
- Devices for collecting exposure measurements across multiple stressors and scales, with an emphasis on high sensitivity and specificity and low-cost devices, when feasible. High-priority analytes include contaminants of emerging concern (*e.g.*, perfluorinated compounds, and toxins produced in harmful algal blooms) as well as ultrafine particulates, microplastics, pesticide exposures, and industrial chemicals.
- Novel sampling technologies to enable subsequent targeted and untargeted laboratory analysis
- Sensor technologies that can be integrated into existing smart devices for sensing personal environment as well as provide chemical speciation data.
- Tools and approaches for identifying and characterizing contaminants in drinking water that may pose a risk to human health, with a particular emphasis on new contaminants

or compounds that are of emerging concern.

**Note that identification of environmental pathogens in drinking water is not within the NIEHS mission.**

### **Computational and Informatics-based Tools and Methods for Exposure Assessment**

- Informatics tools and platforms to organize, store, retrieve, extract, and integrate data on exposures and health effects.
- Application of machine learning methods and natural language processing for extracting and integrating diverse data types and for generating causal networks from experimental data and public knowledgebases
- Computational and statistical approaches to integrate exposure data from different sources, including publicly available databases and information from monitoring approaches (e.g., sensors, remote sensing, and biomonitoring), to provide quantitative exposure estimates, identification, and characterization of adverse effects on human health.
- Adapting or developing new methods and tools for automating environmental health-related literature and systematic reviews, including article selection and prioritization, data extraction, study quality evaluation, and summarization of for environmental health impacts

Additional information can be found on the NIEHS Exposure Biology and the Exposome Program website [Exposure Biology and the Exposome \(nih.gov\)](#)

### **Nano Environmental Health and Safety**

The NIEHS Nano Environmental Health and Safety (Nano EHS) program is interested in the detection of engineered nanomaterials (ENMs) in the environment, in consumer products, and in biological samples, and is interested in technologies or methods that can predict toxicity potential of ENMs.

High priority engineered nanomaterials of interest are those with a potential for human exposure.

Examples include:

- Sensors, tools or technologies that can detect metal and carbon-based engineered nanomaterials or micro/nanoplastics in air, water, and consumer products, and provide a contextual assessment of the toxicological potential.
- Mid- to high-throughput and high-content assays using *in vitro* or tissue chip technologies to screen and rank toxicity of emerging engineered nanomaterials for cytotoxicity, genotoxicity, and metabolic or other human relevant toxicity.
- Methods and tools to assess leaching of engineered nanomaterials from nanotechnology-based water filtration systems.
- Technologies to assess the life cycle of nanomaterials from nano-enabled products in the market
- Development of tools and technology platforms for the isolation, quantification, physical and chemical characterization of various forms of micro/nanoplastics from diverse media including biological samples, aqueous sources, air and food samples and assessment of their toxicity potential and human health effects

Information on the Nano EHS program can be found at [Nano Environmental Health and Safety \(nano EHS\)](#)

## Toxicity Screening, Testing, and Modeling

NIEHS supports research to identify the hazards, as well as the mechanistic understanding, of the effects of environmental stressors on biological systems that can lead to adverse human health outcomes. To increase the ability to characterize or predict the toxicity and hazard of environmental stressors, the National Toxicology Program (NTP) [Home - National Toxicology Program \(nih.gov\)](#) at NIEHS is interested in technologies to support the goals and initiatives of the Tox21 Program [Tox21 \(nih.gov\)](#).

Technologies that support Tox21 and other NTP goals may include the development and/or application of *in vitro* physiologically relevant cell-based systems that effectively model responses in humans or animals and may be used to reduce or replace *in vivo* animal use. High priority areas are the development of metabolically competent *in vitro* screening models and assay systems for various tissue types (e.g., cardiac, neurological, liver, GI tract, kidney, mammary gland, lung, and immune function) for assessing the effects of the environmental stressors.

## Toxicity Screening Approaches

- Improved or new approach methodologies (NAMs) including human organotypic culture models (OCM), and microphysiological systems (MPS) that more accurately predict *in vivo* function for characterizing toxicity and/or related disease processes. Priority areas are improved capability for generating more mature cells from embryonic stem (ES) or induced pluripotent (iPS) cells for organotypic models, integrating multiple MPS together under physiologically relevant conditions, and the ability to conduct *in vitro* pathology studies using OCM, MPS or 3D culture models.
- Organotypic models using cells from rat or mouse models or other experimental animal models, with a focus on comparisons between *in vivo* and *in vitro* toxicity endpoints.
- Approaches to characterize and integrate key molecular and cellular changes related to effects of toxicant exposures in carcinogenicity, developmental neurotoxicity, cardiotoxicity or immune functions.
- *In vitro* model systems that incorporate barrier functionality and transport functions into tissue models (e.g., kidney, placenta, or blood-brain barrier)
- Enhanced lower organism models (e.g., zebrafish or *C. elegans*) for toxicity screening.
- Stem cell models and assays for evaluating the effects of toxicants on cell differentiation with multiple functional endpoints.
- Screening systems that incorporate genetic diversity into toxicology testing (e.g., panels of tissue-specific human iPS cells or rodent stem cells)
- *In vitro* systems that focus on responses to mixtures of xenobiotics, chronic exposure studies, or provide insights into the molecular characteristics of multiple chemical-biological interactions and toxicodynamics.
- Short-term tests, assays, or systems designed specifically to reduce or replace existing regulatory animal studies for acute toxicity (oral or inhalation), reproductive or developmental toxicity, carcinogenicity, or ocular toxicity.

- Cage-based technologies to monitor physiological and behavioral changes in experimental animals in chemical toxicology studies.

### **Computational Approaches for Predictive Toxicology**

- New computational systems and tools for integrating toxicity data, including *in vivo* and *in vitro* data, to analyze and visualize data across different screening systems and predict chemical hazard/risk.
- Computational tools to integrate and visualize transcriptomic and metabolomic data in affected signaling and biochemical pathways.
- Improved computational tools for *in vitro* to *in vivo* extrapolation of xenobiotic exposures and modeling metabolic transformation of xenobiotics.
- Advanced computational approaches (e.g., artificial intelligence/machine learning) to integrate and develop multi-omics classifiers for exposures and pathology image analysis tools for environmentally induced diseases.

### **Other Technologies Focused on Enhancing Toxicology Testing**

- Alternative or improved methods for fixing and preserving tissues that maintain cellular structure for histopathology while minimizing degradation of nucleic acids (RNA, miRNA, DNA, methylated DNA), proteins or metabolites, so that archival tissue blocks can be better used for molecular analysis.
- Liquid biopsy methods for isolation and novel assays of circulating nucleic acids that reflect environmental chemical exposures or toxicity. These could include exosome-packaged or cell-free nucleic acids altered by environmental exposures.
- Alternative or improved methods for extracting high quality RNA, miRNA, DNA, methylated DNA, proteins, or metabolites from existing archived tissues.
- Tools and technologies for isolation and characterization of exosome and/or extracellular microvesicles from biological fluids

### **Biomarkers of Exposure and Response**

To better understand the risks to human health from environmental agents, NIEHS supports the development and validation of biomarkers of exposure, including improved measures of internal dose, DNA adduct identification, and untargeted analysis for metabolite identification, and biomarkers of response, including assays that can distinguish reversible from irreversible changes in target organs or surrogate tissues. Examples include:

#### **Biomonitoring Technology**

- Personal or point-of-care monitoring technologies for rapid detection of multiple exposures in biospecimens using non- or minimally invasive approaches.
- Improved methods to detect DNA or protein adducts resulting from exogenous exposures.
- Exposure assessment methods in novel matrices or small volumes

## **Biological Response Markers**

- Markers of oxidative stress, inflammation, DNA damage response, immune function, mitochondrial dysfunction, or altered epigenetic regulation.

High priority human biomarkers include, but are not limited to inflammation biomarkers, plasma- or serum-based markers that reflect altered RNA, protein expression, or metabolite profiles, markers developed in exhaled breath, buccal cells, or other easily accessible, non-invasive biological samples, miRNA or other exosome biomarkers, and epigenetic markers in surrogate tissue reflecting modifications in target tissues.

## **Intervention Technologies**

NIEHS supports efforts to prevent or reduce exposures to environmental chemical stressors that affect human health. Technologies to reduce exposure may include:

- Technologies for detecting and/or removing contaminants from drinking water, primarily for home use.
- Approaches for use in the home, workplace, and school settings for reducing volatile compounds and other inhaled toxicants. Examples may include improved air filtration systems as well as technologies to monitor the efficacy of filtration systems.
- Technologies and applications that can provide real-time alerts about relevant environmental exposure levels for sensitive populations (such as asthmatic populations)

## **Education and Participatory Science**

As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing tools that build capacity, improve environmental health literacy, and support participatory science endeavors. These approaches or resources should be fit for purpose to meet the needs of the following audiences: community members, health care and public health professionals, educators, and students of all ages. Approaches may include:

- Mobile applications that provide environmental health information about exposures of concern in food, air, drinking water, or consumer products. These may include
  - Interactive apps that provide the context and risks of exposures such as single or multiple, interacting exposures, level of exposure, frequency and proximity to source and health risks
  - Apps that can be adapted for various age groups, races, ethnicities and/or languages.
- Devices for collecting and reporting information on exposures in environmental samples for educational purposes in schools or communities.
- Systems that can utilize public and voluntary population data from sensors, activity trackers, GIS enabled devices, social communications, and surveillance cameras; for example, to assist disaster response and communication.
- Educational resources and tools related to environmental health in school settings or community education programs.

- Training materials for wider dissemination of risk information (e.g., resources for high school students or community leaders to build capacity of other community residents)

Information on the PEPH program can be found at [Partnerships for Environmental Public Health \(PEPH\) \(nih.gov\)](#).

## **Other Areas of Interest**

### **Exposure and Response to Vaping and Electronic Nicotine Delivery Systems (ENDS)**

NIEHS is interested in technologies to assess exposure to aerosols from e-cigarettes and other vaping devices, including analyses of the chemical constituents in these aerosols. In addition, approaches to test the toxicity and biological responses to ENDS aerosol constituents are of interest.

### **Disaster Response**

NIEHS is interested in sensors and informatics tools that can be rapidly deployed after disasters, including extreme weather events or climate change-related events. These tools can be used by researchers to follow emergency response workers and individuals in the community to help understand dermal, water and/or airborne exposure levels, locations, and times.

- Environmental sensors that can be rapidly deployed during or after a disaster to track exposures.
- Informatic tools to rapidly build environmental health disaster research protocols similar to the NIEHS RAPIDD Protocol [Disaster Research Response \(DR2\) Program \(nih.gov\)](#) from existing information, tools, and platforms (e.g., PhenX, PROMIS, and Disaster Research Response DR2 Repository) to support rapid research response efforts
- Data management tools for disaster response that enable rapid collation and integration of data from stationary sources and personal exposure monitors and survey information collected from individuals.
- Mobile devices and applications for collecting information on environmental exposures from study participants involved in disaster research responses.

### **Hazardous Substances Remediation and Site Characterization SBIR Program**

The NIEHS Superfund Research Program (SRP) "Hazardous Substances Remediation and Detection Program" supports Small Business Innovation Research Grants (SBIR R43, R44) to foster the commercialization of novel, cost-competitive technologies, products, and devices for remediation and detection of hazardous substances in the environment. The SRP is specifically interested in proposals applying new engineering, materials science, and biotechnology approaches. In addition, applicants are encouraged to develop sustainable strategies such as offering low carbon footprint, reduced energy consumption, utilization of renewable energy sources, resilient to weather extremes, and with reuse / regeneration capabilities.

### **Remediation**

- Novel technologies for in situ remediation of contaminated sediments, soils, and groundwater with testing/modeling to optimize product for long-term stability
- Innovative bioremediation technologies including development and culturing/propagation of novel plants, bacterial strains, or fungal species for implementing bioremediation



- Technologies to remediate chemical mixtures in environmental media
- New strategies for delivery of reagents/amendments for groundwater remediation and/or recovery/extraction of contaminants in groundwater
- New amendments to stabilize contaminants and/or to use in caps for soil and sediment remediation
- New technologies and strategies to cleanup large complex sites with multiple sources
- Resilient novel remediation approaches capable of withstanding climate change-related impacts such as: fire, flooding groundwater level fluctuation, land use changes, and other catastrophic events
- Sustainable, energy efficient approaches with a net lifecycle benefit such as net zero emission technologies; technologies that reduce waste generation; processes that recycle/reuse/regenerate active components; long-term remediation approaches equipped with solar or wind energy

### **Detection Technologies**

- Machine learning, computational, geographical information system-based, or modeling products for predicting fate and transport of contaminants, rates of remediation, bioavailability, or for identifying contamination sources
- Real-time, field deployable, on-site analysis: soil, surface water, groundwater, subsurface, sediments, air (such as volatile releases from sites), including
  - rapid, portable monitoring and screening of contaminants
  - multi-analyte sampling
  - remote monitoring/data capture/data processing capabilities such as time-integrated and/or repeated measures
- Accurate and reliable new passive sampler devices
- Products that allow for rapid sample clean-up/preparation for analysis of environmental samples and/or technologies for rapid extraction or processing of soil for incremental sampling methodologies (ISM)
- Non-targeted or multi-analyte field sampling devices or kits, including sample collection products that can sequester a suite of analytes for later analysis
- Novel techniques, sensors, and field analytical methods and real-time mapping/data visualization for development of subsurface conceptual site models
- Innovative tracer technologies for tracking contaminant migration/pathways

### **Examples of remediation and detection technology needs:**

- Vapor Intrusion: Improved technologies for predicting/anticipating time-periods for occurrence of reasonable maximum indoor exposure(s) in impacted buildings, during which sampling is recommended.
- PFAS: Soil, sediment, and groundwater remediation technologies for mixtures and degradation byproducts of per- and polyfluoroalkyl substances (PFAS); including technologies for complete PFAS destruction; sustainable solutions with low energy input

and/or minimal secondary waste generation; and/or PFAS removal technologies for heterogeneous water chemistries; rapid sensors to aid in site monitoring and/or prioritizing site sampling protocols.

- Novel, sustainable, nontoxic chemistries or processes to aid regeneration, reuse, and/or reactivation of spent treatment residues (e.g., from granular activated carbon).
  - Development of adsorption and concentration materials to reduce the volume of material to be treated and/or to further concentrate the waste stream generated from standard treatment technologies (e.g., granular activated carbon, reverse osmosis) as part of a “treatment train”.
  - Development of polishing treatments tailored for specific PFAS (e.g., shorter chain, emerging PFAS replacements).
  - Development of novel catalysts or other additives to lower needed temperature for complete thermal destruction.
  - Development of novel air pollution control technologies as a polishing step to reduce emissions from PFAS management or treatment facilities (e.g., thermal destruction, air sparging, Supercritical water oxidation (SCWO), hazardous waste landfill facilities, etc.).
  - Development of novel materials or processes for solid waste and/or biosolids treatment and/or stabilization.
- Mining: Active or passive remediation technologies for mining influenced water; technologies to mitigate effects from acid drainage; portable neutralization treatment systems; strategies to target remediation of sources such as mining waste piles; and separation technologies that remove elements or compounds of concern from water and/or reclaim potentially valuable critical elements dissolved in contaminated fluids
  - Complex Site/Geology:
    - Site characterization techniques and strategies for complex geology (fractured bedrock, karst, and heterogeneous layered deposits) including understanding the fate of contaminants within rock matrices and properties that affect back diffusion
    - Improved technologies for treating low permeability and heterogeneous lithology, including amendment delivery methods
    - Devices to detect and measure non-aqueous phase liquids (NAPLs) in the subsurface
    - In-well real-time and/or continuous monitoring tools to assess the efficacy of remediation; presence/absence of key factors required for remediation (e.g., biological, geological, chemical); and/or to identify rebound events
    - Robotic sampling for highly contaminated / remote sites
  - Disaster Response: Technologies for measuring/treating environmental contamination as part of a disaster response effort

Applicants must demonstrate that the proposed technologies are relevant to Superfund and/or other sites impacted by hazardous substances. Per program mandates described in the Superfund Amendment Reauthorization Act (SARA), SRP does not accept applications targeting oil or gas site characterization/remediation. Applicants are strongly encouraged to stay within total funding support (direct costs, indirect costs, and fees) does not exceed \$183,460 for Phase I awards and \$1,223,064 for Phase II awards. Applicants are encouraged to contact NIH program officials prior to submitting any award budget for the "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research Program" in excess of these amounts. For budgetary, administrative, or programmatic reasons, NIEHS may decide not to fund an application or may decrease the length of an award and/or the budget. NIEHS will consider well justified Technical and Business Assistance (TABA) costs up to the limits specified on the [NIH SEED website](#). These costs can be requested in addition to

the Phase I and II limits indicated above. These costs can be requested in addition to the Phase I and II limits indicated above. **Please note: the NIEHS Superfund Research Program (SRP) "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research Program" no longer accepts Small Business Technology Transfer Grant (STTR: R41, R42) applications.** Funding decisions will be made based on programmatic need with an emphasis on novel technologies distinct from [current or recently-funded SBIR grants](#) that are applicable to Superfund and/or other sites impacted by hazardous substances.

Please visit the "Small Business Innovative Research Grants (R43/R44) Hazardous Substances Remediation and Site Characterization SBIR Program" section on the following webpage: <https://www.niehs.nih.gov/research/supported/centers/srp/funding>.

## **Worker Training Program**

The major objective of the NIEHS Worker Training Program (WTP) is to prevent work related harm by training workers in how best to protect themselves and their communities from exposure to hazardous materials. The NIEHS WTP is interested in the development of e-Learning Technology- Enhanced Training Products from a variety of delivery methods to assist both students and instructors in the training and education process. These Technology-Enhanced Training Products are for the health and safety training of hazardous materials (HAZMAT) workers; waste treatment personnel; skilled support personnel associated with an emergency/disaster; emergency responders in biological hazard response, infectious disease response and medical waste cleanup; emergency responders in disasters; and worker resiliency training. Technology-Enhanced Training Products as defined by the WTP includes, but are not limited to, online training, mobile device training, augmented reality (AR), virtual reality (VR), and serious gaming. These advanced technologies complement all aspects of training that can enhance, supplement, improve, and provide health and safety training for hazardous materials workers. **WTP accepts solicitations via requests for applications (RFA).** Please contact Kathy Ahlmark ([ahlmark@niehs.nih.gov](mailto:ahlmark@niehs.nih.gov)) for information on the next solicitation date, which differs from the standard receipt dates of this NIH omnibus.

Information on the WTP program can be found at [About the Worker Training Program \(WTP\) - Training for Workers in Hazardous Environments \(nih.gov\)](#)

## **NIEHS Clinical Trials Topics:**

NIEHS will accept SBIR/STTR applications that propose clinical trials related to:

- Development and testing of sensor technology, biomarkers, or biomonitoring technologies, including field testing of new technologies for exposure assessment and biological responses to environmental exposures.
- Evaluation of tools or approaches for education and dissemination of information on environmental hazards, including evaluation of changes in behavior.

## **Contact Information**

For additional information on research topics, contact:

Dr. Daniel Shaughnessy  
National Institute of Environmental Health Sciences  
Division of Extramural Research and Training  
POB 12233 (K3-12)  
Research Triangle Park, NC 27709  
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For information on the NIEHS Superfund Research Program -  
Hazardous Substances Remediation and Site Characterization  
SBIR Program, contact:

Dr. Heather Henry  
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For administrative and business management questions contact:

Mr. Clark A. Phillips  
National Institute of Environmental Health Sciences  
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## **NATIONAL EYE INSTITUTE (NEI)**

### **Mission**

The mission of the NEI is to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, the special health problems and requirements of the blind, and providing eye health care to underserved populations.

For up-to-date information on priority research areas of scientific interest to the NEI, please visit our [home page at http://www.nei.nih.gov](http://www.nei.nih.gov).

### **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). For budgetary, administrative, or programmatic reasons, NEI may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. For topics listed in [SBA-Approved Waiver Topics](#), NEI does not generally fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; or Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. Applicants are strongly encouraged to contact program officials prior to submitting any application in excess of the hard caps listed above and early in the application planning process.

### **Specific SBIR and STTR Program Information**

The NEI's programs are described in more extensive detail in documents which are available from the Institute. For additional information about the research programs of the NEI, please visit our home page at <http://www.nei.nih.gov>.

### **Phase IIB Competing Renewal Awards and Commercial Readiness Pilot (CRP)**

The NEI will only accept SBIR Phase IIB Competing Renewal grant applications from Phase II SBIR awardees to continue the process of developing technologies that ultimately require federal regulatory approval or require extraordinary time and effort in the Research and Development phase. Such technologies include, but are not limited to, pharmacologic agents, biological products, and devices. These technologies should be clearly related to the mission of the NEI. This renewal grant should allow small businesses to reach a stage in the project where interest and investment by third parties is more likely. The NEI expects that the Phase IIB grant will accelerate the transition of SBIR Phase II projects to the commercialization stage. The NEI encourages applicants to establish business relationships with third-party investors and/or strategic partners who can provide substantial financing to help accelerate the commercialization of promising new products and technologies that were initiated with SBIR funding.

The Competing Renewal application must be a logical extension of a previously completed Phase II (R44) SBIR grant. NEI grantees seeking SBIR Phase IIB Competing Renewal funding must submit an application within a period no later than the first six receipt dates following expiration of the previous Phase II budget period. Cumulative budgets should not exceed \$1,800,000 total costs, or time periods beyond three (3) years.

Although matching funds are not required, the NEI strongly encourages that applicants obtain significant private investment. Competitive preference and funding priority will be given to

applicants that demonstrate the ability to secure substantial independent third-party investor funds.

Applicants are strongly encouraged to contact the NEI Program Officer, Dr. Paek Lee (contact information provided below) prior to submitting any application in excess of the hard caps listed above and early in the application planning process.

### **Clinical Trials**

Does NEI accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	Minimal risk clinical trials only. See details below.
Does NEI accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	U44 <a href="#">PAR-24-066</a>
Does NEI support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	R01 <a href="#">PA-20-183</a> UG1 <a href="#">PAR-21-042</a> , <a href="#">PAR-21-043</a> , <a href="#">PAR-21-041</a> U01 <a href="#">PAR-22-149</a>

NEI accepts clinical trial applications submitted under SBIR and STTR Omnibus/Parent Clinical Trial Required Notices of Funding Opportunities that include human subjects prospectively assigned to one or more interventions that are minimal risk as defined by 45 CFR 46. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. As part of the review process, the application must include a clear, detailed plan for monitoring safety that is commensurate with the risks to study participants. In addition to the minimal risk designation from the Institutional Review Board, other reporting to the NEI may be required and will be outlined in the Notice of Award Terms and Conditions.

Applicants who wish to submit greater-than-minimal risk, complex, large-scale, high-resource or safety-risk clinical trials that propose to test efficacy, effectiveness or safety should not submit to these NOFOs. Instead, early-stage clinical trial applications with greater than minimal risk to subjects must be submitted to PAR-24-006 NEI Small Business Innovation Research (SBIR) Cooperative Agreement for Early-Stage Clinical Trials with Greater than Minimal Risk (U44-Clinical Trial Required). Complex, large-scale, high-resource clinical trials must be submitted to one of the Clinical Research cooperative agreement NOFOs listed here: <https://www.nei.nih.gov/grants-and-training/funding-opportunities/current-funding-opportunities>.

### **Research Topics**

- A. General Research and Development Topics:** NEI is interested in providing support for the development of new technologies, strategies, research tools, reagents and methods that can be applied to basic and translational research which will benefit vision health. This encompasses research and development of innovative enabling technologies in areas of genomics, proteomics and nanotechnology. More specific topics include drug and high throughput assays; drug delivery systems; gene therapy, cell-based therapy and regenerative medicine; development of in vitro and in vivo disease models; surgical devices and materials; telemedicine, mobile health, and health education; and design/fabrication of new or improved ophthalmic instruments for diagnosis and treatment of eye disorders.
- B. Retinal Diseases:** New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid; Better methods of diagnosing and treating diabetic retinopathy and other vascular diseases; Non-invasive techniques for early

diagnosis of macular degeneration and other retinal degenerative diseases; Instruments and procedures for improved surgical management of retinal detachments; Retinal prostheses to help restore visual function; Gene therapy/optogenetic methods for light sensitivity restoration in the retina; Better methods for cell or tissue transplantation; New animal models/systems that better mimic human retinal disease.

- C. **Corneal Diseases:** New diagnostic tools, therapeutic agents and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders; New biomaterials for corneal prostheses and corneal transplants; Instruments and procedures for correcting the refractive power of the cornea and/or measuring the cornea's optical properties or other physiological properties.
- D. **Lens and Cataract:** New approaches in the post-operative management of cataract surgery; New surgical instruments for cataract extraction and new biomaterials for replacement of the natural lens; Design/fabrication of aspheric, toric, multifocal and accommodating intraocular lenses.
- E. **Glaucoma and Optic Neuropathies:** New therapeutic agents, instruments, and procedures for the diagnosis and treatment of glaucoma; Non-invasive methods to measure changes in the optic nerve head and retinal fiber layer.
- F. **Strabismus, Amblyopia, and Refractive Error:** New approaches to detect and treat strabismus, amblyopia, and myopia; New tools and techniques for vision screening; New or improved methods and materials for correcting the refractive power of the eye and/or measuring the eye's optical properties or other physiological properties; New materials and manufacturing processes for eyeglasses and contact lenses; prosthetic devices (both cortical and subcortical) for vision restoration.
- G. **Visual Impairment and Blindness:** Instruments and methods to better specify, measure, and categorize residual visual function; New or improved devices, systems, or programs that meet the rehabilitative, adaptive, and everyday living needs of visually impaired/blind people.

#### **Contact Information**

For more information on research topics, contact:

##### **Paek Lee, Ph.D.**

Program Director, Small Business  
SBIR/STTR Division of Extramural Science Programs  
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6700B Rockledge Drive  
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##### **Tony D. Gover, Ph.D.**

Program Director, Small Business SBIR/STTR (Anterior Segment)  
Division of Extramural Science  
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For administrative and business management questions, contact:

**Ms. Karen Robinson Smith**  
Chief Grants Management Officer  
Grants Management Branch  
Division of Extramural Activities  
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# NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

## **Mission**

NIGMS supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS-funded scientists investigate how living systems work at a range of levels—from molecules and cells to tissues and organs—in research organisms, humans, and populations. Additionally, to ensure the vitality and continued productivity of the research enterprise, NIGMS provides leadership in training the next generation of scientists, enhancing the diversity of the scientific workforce, and developing research capacity throughout the country.

All NIH institutes and centers support basic research that's relevant to the diseases, organ systems, stages of life, or populations within their mission areas. In contrast, NIGMS supports fundamental research that doesn't focus on those specific areas. Its research mission is aimed at understanding the principles, mechanisms, and processes that underlie living organisms, often using research models.

NIGMS also supports the development of fundamental methods and new technologies to achieve its mission. Supported research may utilize specific cells or organ systems if they serve as models for understanding general principles.

NIGMS also supports research in specific clinical areas that affect multiple organ systems: anesthesiology and peri-operative pain; sepsis; clinical pharmacology that is common to multiple drugs and treatments; and trauma, burn injury, and wound healing.

The Institute is organized into divisions that support research, research training, and capacity building in a range of scientific fields. To find out more information on the participating divisions and the research supported, please visit the following links:

[Division of Biophysics, Biomedical Technology, and Computational Biosciences](#)

[\(BBCB\) Division of Pharmacology, Physiology, and Biological Chemistry \(PPCB\)](#)

[Division for Research Capacity Building \(DRCB\)](#)

[Division of Training Workforce Development, and Diversity \(TWD\)](#)

## **Budget Guidance**

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). NIGMS will not accept applications with budget requests exceeding this hard cap with the exception of projects that fit within the [SBA-Approved Waiver Topics](#) list for awards over the statutory budget limitations. NIGMS sets its own budget limits for the specific research topics that are granted a waiver to exceed the U.S. Small Business Administration hard budget caps. The NIGMS budget limit for a Phase I project on an approved topic is \$350,000 in total costs with a project period up to 1 year. The budget limit for a Phase II project on an approved topic is \$2,500,000 in total costs for a project period up to 3 years. If considering a project with a budget exceeding the hard cap, applicants are strongly encouraged to contact NIGMS program officials prior to submission, and preferably in the early stages of application preparation. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

## **Specific SBIR and STTR Program Information**

<https://www.nigms.nih.gov/grants-and-funding/research-funding/small-business-research>

### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIGMS will accept Phase IIB SBIR-only Competing Renewal grant applications to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, or 3) continuing refinements that include but are not limited to cost reduction, testing for performance, safety, reliability and/or durability, and meeting or establishing standards, particularly for basic or clinical research instrumentation or durable medical equipment (DME) designs. This renewal grant should enhance the likelihood that small business will attract interest and investment by third parties. Such products include, but are not limited to research equipment, biological products, devices, drugs, medical implants, etc. within the mission of the NIGMS. Budgets for this Phase IIB Competing Renewal opportunity must follow the guidelines for Phase II applications (described above). For awards that are intended to support completion of research needed to obtain an Investigational New Drug application (IND) or Investigational Device Exemption (IDE), applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements.

Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes. Applicants should describe these consultations and the outcomes in the Progress Report section of the Research Strategy and provide FDA correspondence or meeting minutes as part of Just-in-Time procedures.

Prospective applicants considering a Phase IIB Competing Renewal application are strongly encouraged to contact either the Program person of record for the Phase II award or NIGMS contacts listed at the end of this NIGMS topics announcement.

To assist NIGMS in planning for Phase IIB applications, it is helpful for prospective applicants to submit to the NIGMS Small Business Strategy Coordinator (listed below) a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Phase II grant number
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Notice of Funding Opportunity Number

The letter is non-binding and does not enter the review process. It is anticipated that only a small number of NIGMS SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal award.

### **Clinical Trials**

Does NIGMS accept Clinical Trials through the Omnibus /Parent Notices of Funding Opportunities?	No	
Does NIGMS accept Clinical Trials through specific Notices of Funding Opportunities	No	
Does NIGMS support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	PA-20-206 <a href="https://grants.nih.gov/grants/guide/pa-files/PA20-206.html">https://grants.nih.gov/grants/guide/pa-files/PA20-206.html</a>  PA-20-183 <a href="https://grants.nih.gov/grants/guide/pa-files/PA20-183.html">https://grants.nih.gov/grants/guide/pa-files/PA20-183.html</a>

### **Contact Information**

For general information on the NIGMS Small Business program, contact:

Eddie Billingslea, Ph.D., NIGMS Small Business Strategy Coordinator  
Email: [NIGMS\\_SmallBusiness@nigms.nih.gov](mailto:NIGMS_SmallBusiness@nigms.nih.gov)

For scientific questions about NIGMS-funded SBIR/STTR research, contact:

DIVISION OF PHARMACOLOGY, PHYSIOLOGY, AND BIOLOGICAL  
CHEMISTRY

Pharmacological and Physiological

Sciences Sailaja Koduri, Ph.D.

Email: [Sailaja.Koduri@nih.gov](mailto:Sailaja.Koduri@nih.gov)

Biochemistry and Bio-related

Chemistry Kadir Aslan, Ph.D.

Email: [kadir.aslan@nih.gov](mailto:kadir.aslan@nih.gov)

DIVISION OF BIOPHYSICS, BIOMEDICAL TECHNOLOGY, AND COMPUTATIONAL BIOSCIENCES

Ashley Barnes, Ph.D.

Email: [ashley.barnes@nih.gov](mailto:ashley.barnes@nih.gov)

DIVISION OF TRAINING, WORKFORCE DEVELOPMENT, AND DIVERSITY

Sailaja Koduri, Ph.D.

Email: [Sailaja.Koduri@nih.gov](mailto:Sailaja.Koduri@nih.gov)

DIVISION FOR RESEARCH CAPACITY BUILDING

Krishan Arora, Ph.D.

301-435-0763

Email: [arorak@nigms.nih.gov](mailto:arorak@nigms.nih.gov)

Research and Development in Science Education

Tony Beck, Ph.D.

301-480-4623

Email: [beckL@mail.nih.gov](mailto:beckL@mail.nih.gov)

For administrative and business management questions, contact:

ADMINISTRATIVE AND BUSINESS MANAGEMENT

Mr. Brian Iglesias

301-451-5903

Email: [iglesiab@mail.nih.gov](mailto:iglesiab@mail.nih.gov)

Ms. Ilene Glassman

301-594-4648

Email:

[ilene.glassman@nih.gov](mailto:ilene.glassman@nih.gov)

[v](#)

Ms. Alania Foster

301-451-8255

Email: [Alania.foster@nih.gov](mailto:Alania.foster@nih.gov)

# NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

## Mission

The NHLBI plans, conducts, and supports research, clinical trials, demonstration, and educational projects related to the causes, prevention, diagnosis, and treatment of heart, lung, blood, and sleep disorders. It also supports research on the clinical use of blood products and all aspects of the management and safety of blood resources. The NHLBI SBIR/STTR programs foster basic, applied, and clinical research on all product and service development related to the mission of the NHLBI. The NHLBI has four extramural program divisions, described below. For more information on the NHLBI Strategic Vision, visit: [https://www.nhlbi.nih.gov/sites/default/files/2017-11/NHLBI-Strategic-Vision-2016\\_FF.pdf](https://www.nhlbi.nih.gov/sites/default/files/2017-11/NHLBI-Strategic-Vision-2016_FF.pdf).

For the most up-to-date information on the NHLBI Small Business Programs, please visit the NHLBI SBIR/STTR website: (<https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/small-business-program>) and subscribe to our [listserv \(http://bit.ly/NHLBI-SBIR-Updates\)](http://bit.ly/NHLBI-SBIR-Updates). You can also follow us on X at [@NHLBI\\_SBIR](https://twitter.com/NHLBI_SBIR). NHLBI encourages potential applicants to contact us at: <http://bit.ly/ContactNHLBIsbir>.

## Budget Guidance

Total funding support (direct costs, indirect costs, and fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). For budgetary, administrative, or programmatic reasons, the NHLBI reserves the right to disapprove funding or decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NHLBI that can be found in the [SBA-Approved Waiver Topics](#). It is strongly recommended for applicants who have a project that falls under one of the SBA-Approved Waiver Topics to reference the corresponding topic in their Budget Justification document. For most projects falling under one of the SBA-approved waiver topics, the NHLBI does not fund Phase I applications greater than the current SBA-mandated budget guidelines (up to \$306,872 total costs for Phase I and up to \$2,045,816 total costs for Phase II applications). However, the NHLBI may **occasionally** fund projects above these guidelines for proposals falling under one of the approved waiver topics if **one or more** of the following criteria have been fulfilled:

1. The application involves the clinical testing of therapeutics, devices, imaging agents, biologics, diagnostics, clinical and rehabilitation tools, and/or technologies.
2. The application involves the use of a large animal model. For the purpose of this guidance, large animal model species include: swine (porcine), sheep (ovine), cattle (bovine), cat (feline), dog (canine), ferret, and nonhuman primates.

Applicants with budget requests exceeding these caps **should be prepared to negotiate their budget down** if their proposal does not fall into one of the above categories.

Furthermore, all applicants with budget questions, or considering requesting a budget greater than the set budget limitation amounts, are **strongly encouraged** to contact the NHLBI SBIR office at <http://bit.ly/ContactNHLBIsbir> before submitting an application. For more information on the NHLBI Budget Policy for SBIR/STTR grants, please refer to [NOT-HL-24-008](#).

### **Specific SBIR and STTR Program Information**

The NHLBI encourages applications proposing innovative technologies related to any area within the NHLBI mission.

The NHLBI maintains a [list of Notices of Special Interest \(NOSIs\)](#) and funding opportunities that are specific to the Institute. Instructions for submitting applications in response to these topics are posted on the web page. The list is revised throughout the year, so please check regularly for updates.

For more information, contact the NHLBI Small Business team at <http://bit.ly/ContactNHLBIsbir> or the Division contact associated with your technology area listed at the end of the NHLBI section.

### **Technical and Business Assistance**

Applicants can request funding for technical and business assistance (TABAs) in their application. Small businesses should include this budget request as part of the application and provide a detailed description of the vendor and services in the Budget Justification. TABA costs may be requested in addition to the Phase I and II budget caps set by the NHLBI. The NHLBI may also fund TABA costs through the administrative supplement program ([PA-20-272](#)). For more information about requesting TABA funding through administrative supplements, please contact Dr. Jain Krotz at [jain.krotz@nih.gov](mailto:jain.krotz@nih.gov).

### **Interim and Final Progress Reports**

As detailed in [NOT-OD-17-085](#), the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NHLBI is interested in tracking the progress of the small business concerns it funds and the products they develop. Funding priority will be given to those small business concerns that show both their ability to develop products and their growth as a small business concern towards independence from the SBIR/STTR program.

Additionally, the NIH requires all SBIR/STTR grantees to submit their Life Cycle Certification document with their Interim Research Performance Progress Reports (Interim RPPR). For more information on this requirement, please reference [NOT-OD-19-025](#).

### **Specific Funding Opportunities and Programs**

The NHLBI encourages applications focused on innovative technologies that align with its Mission (<https://www.nhlbi.nih.gov/about/mission-statement>) through the Omnibus Notices of Funding Opportunity (NOFOs). In addition to this Omnibus program announcements, the NHLBI releases targeted NOFOs and Notices of Special Interest (NOSIs) throughout the year. Sign up for the [listserv](#) (<http://bit.ly/NHLBI-SBIR-Updates>) to be notified of new NOFOs and NOSIs. Please note that NOFOs and NOSIs can be released or expire at any time throughout the year; please refer to the [NHLBI SBIR/STTR website](#) for active announcements supported by NHLBI.

### **Programs and Services for NHLBI Small Business Awardees**

The NHLBI offers free assistance to applicants and awardees regarding intellectual property, commercialization, and business plan development. Please visit <https://nhlbi.my.salesforce-sites.com/> to request services.

The NHLBI hosts “Small Biz Hangouts” - a free educational series covering the basics of biomedical technology development. Previous Hangouts are archived on the NHLBI YouTube channel Small Business Resources [playlist](#). Sign up for the NHLBI [listserv](#) (<http://bit.ly/NHLBI-SBIR-Updates>) to learn about upcoming live events, program announcements. Learn more about available resources at

<http://www.nhlbi.nih.gov/about/org/dera/otac/resources>.

## **Regulatory and Commercialization Guidance for Phase II and Fast-Track Applicants**

The NHLBI strongly encourages applicants to include a robust regulatory strategy with corresponding milestones in Phase II and Fast-Track applications. Applicants are also encouraged to include letters of support or other evidence documenting their regulatory strategy. Furthermore, the NHLBI **also strongly encourages** applicants to describe the following elements in their commercialization plan: management team, market size/opportunity, competitive advantage, intellectual property, potential impact on healthcare costs and outcomes, pricing and reimbursement strategy, the clinical trial plan (if applicable), and the proposed go-to-market strategy for the technology. **The NHLBI will consider the strength of these elements when making funding decisions for Phase II and Fast-Track applications.** For more information on additional factors that are involved with making funding decisions for Phase II SBIR/STTR applications and other applications funded through the Zone of Consideration, please visit <https://www.nhlbi.nih.gov/current-operating-guidelines>.

For assistance regarding the Phase II commercialization plan, watch the “Small Biz Hangout” for advice on [Writing Your Phase II Commercialization Plan](http://bit.ly/Ph2CommPlanHangout) (<http://bit.ly/Ph2CommPlanHangout>) and contact Stephanie Davis ([nhlbi\\_sbir@mail.nih.gov](mailto:nhlbi_sbir@mail.nih.gov)) with specific questions.

## **Phase IIB Competing Renewal Awards**

NHLBI only accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities. These opportunities can be found on the NHLBI Funding Opportunities webpage: <https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/small-business-program>. Applicants are strongly encouraged to contact Dr. Jain Krotz at [jain.krotz@nih.gov](mailto:jain.krotz@nih.gov) for additional information on Phase IIB funding opportunities.

## **Commercialization Readiness Pilot (CRP)**

The NHLBI welcomes the submission of Commercialization Readiness Pilot (CRP) program applications from current or past Phase II/IIB awardees. The CRP aims to facilitate the transition of previously or currently funded SBIR and STTR Phase II and Phase IIB projects to the commercialization stage by providing additional support for technical assistance and later-stage research and development (R&D) not typically supported through Phase II or Phase IIB grants or contracts. NHLBI will accept budgets up to \$500,000 total costs (direct costs, indirect costs, fee) across up to two years. NHLBI participates in the following CRP NOFOs below:

- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Not Allowed ([PAR-23-219](#))
- SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late Stage Development - Clinical Trial Required ([PAR-23-220](#))

## **Clinical Trials**

Does NHLBI accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	Please reach out to program staff at least 30 days before the application deadline to discuss your project if submitting a Clinical Trial application.
Does NHLBI accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	Please reach out to program staff at least 30 days before the application deadline to discuss your project if submitting a Clinical Trial application.

Does NHLBI support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	For information on non-SBIR/STTR clinical trials funding mechanisms for which small businesses are eligible, please visit the <a href="#">NHLBI clinical trials website</a>

## **Research Topics**

### **Cardiovascular Sciences**

The Division of Cardiovascular Sciences (DCVS) supports basic, clinical, population, and health services research on the causes, prevention, and treatment of cardiovascular diseases. The research programs of the Division encompass investigator-initiated research, Institute-initiated research in targeted areas of research need and scientific opportunity, specialized centers of research focused on selected research topics, and clinical trials. Research supported by the Division is concerned with the etiology, pathogenesis, prevention, diagnosis, and treatment of coronary artery disease and atherothrombosis; pediatric and structural heart disease; heart failure and arrhythmias; and hypertension and vascular diseases. DCVS also supports investigations into the development and use of medical devices, imaging devices, software programs, AI/ML technologies, molecular technologies and other tools to improve cardiovascular health. A broad array of epidemiological studies is supported by the DCVS to describe disease and risk factor patterns in populations and to identify risk factors for disease. Also supported are clinical trials of interventions to prevent and treat disease; studies of genetic, behavioral, sociocultural, and environmental influences on disease risk and outcomes; and studies of the application of prevention and treatment strategies to determine how to improve clinical care and public health. If you would like to learn more about the scientific areas covered by the DCVS and connect with a program officer, please visit the division website: [Division of Cardiovascular Sciences | NHLBI, NIH](#).

### **Lung Diseases**

The Division of Lung Diseases (DLD) supports research on the causes, diagnosis, management, prevention, and treatment of lung diseases and sleep disorders. Research is funded through investigator- initiated and Institute-initiated grant and contract programs in areas including asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, critical care and acute lung injury, developmental biology, pediatric and neonatal pulmonary diseases and care, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis. Also supported are mechanistic and non-mechanistic clinical trials to predict, prevent and treat pulmonary disease; digital health including mobile / tele-health, wearable devices, respiratory surgical devices, aerosol drug or gas delivery, supplemental oxygen, bioinformatics, mechanical ventilation, imaging devices, personalized medicine and AI/ML to help inform clinical decision making in pulmonary medicine. If you would like to learn more about the scientific areas covered by the DLD and connect with a program officer, please visit the division website: [Division of Lung Diseases | NHLBI, NIH](#).

### **Sleep and Circadian Biology**

The National Center for Sleep Disorders Research (NCSDR) supports research on the causes, prevention, and treatment of sleep disorders and the promotion of sleep health. Research is funded through investigator- initiated and Institute-initiated, grant, and contract programs in



sleep and circadian biology research projects. The NCSDR is interested in funding projects related to the regulation of sleep and sleep disorders including circadian disorders, insomnia and obstructive sleep apnea. The NCSDR is also interested in research focused on the development of tools, devices and data science approaches for the early prediction, detection, and treatment of sleep deficiency and sleep and circadian disorders. If you would like to learn more about the scientific areas covered by the NCSDR and connect with a program officer, please visit the website: [National Center on Sleep Disorders Research | NHLBI, NIH](#).

### **Blood Diseases and Resources**

The Division of Blood Diseases and Resources (DBDR) supports research on the causes, prevention, and treatment of nonmalignant blood diseases, including anemias, sickle cell disease, hemophilia and thalassemia; premalignant processes such as myelodysplasia and myeloproliferative disorders; and other abnormalities of hemostasis and thrombosis; and immune dysfunction. Research supported by the Division encompasses a broad spectrum of topics ranging from basic biology and mechanism of action, to medical management of blood diseases. The Division has a major responsibility for research to improve the adequacy and safety of the nation's blood supply. It also plays a leading role in transfusion medicine and blood banking, including research to evaluate blood donation screening, manufacturing, processing technologies and storage. The Division also has a major responsibility supporting research in hematopoiesis and stem cell biology and disease. It also supports hematopoietic stem cell transplantation research and the application of stem cell biology findings to the development of new cell-based therapies to repair and regenerate human tissues and organs. If you would like to learn more about the scientific areas covered by the DBDR and connect with a program officer, please visit the division website: [Division of Blood Diseases and Resources | NHLBI, NIH](#).

### **Center for Translation Research and Implementation Science**

The Center for Translation Research and Implementation Science (CTRIS) plans, fosters, and supports an integrated and coordinated program of research to understand the multi-level processes and factors that are associated with successful integration of evidence-based interventions within specific clinical and public health settings such as worksites, communities, and schools; identifies and makes readily available to implementation and dissemination practitioners emergent knowledge about the late phases of translation research, especially the "T4" phase, for rapid and sustained adoption of effective interventions in real world settings; leads the NHLBI effort in the rigorous, systematic evidentiary reviews and subsequent NHLBI participation in the collaborative model for clinical practice guidelines development; supports training and career development of personnel in "T4" translation research and health inequities relating to heart, lung, and blood diseases; provides a focal point for advice and guidance on matters pertaining to minority health, health inequities and minority participation in research; represents the NHLBI to other governments, other Federal Departments and agencies, international organizations, and the private sector on global health issues; and provides data analytics and portfolio analysis to evaluate and inform future directions of implementation research programs. If you would like to learn more about the scientific areas covered by the CTRIS and connect with a program officer, please visit the division website: [Center for Translation Research and Implementation Science | NHLBI, NIH](#).

### **Contact Information**

#### **SBIR OFFICE**

For general questions about the NHLBI SBIR/STTR grant program, please contact:

Stephanie Davis, Ph.D.  
Division of Extramural Research Activities  
Phone: 1-301-496-8412  
Email: [mailto: nhlbi\\_sbir@mail.nih.gov](mailto:nhlbi_sbir@mail.nih.gov)

For administrative and business management questions, please contact:

Andre Walker  
Division of Extramural Research  
Activities Phone: 1-301-827-8061  
Email: [walkera@nhlbi.nih.gov](mailto:walkera@nhlbi.nih.gov)

**CARDIOVASCULAR SCIENCES**

Rahul Thakar, Ph.D.  
Division of Cardiovascular Sciences  
Advanced Technologies and Surgery Branch  
Phone: 301-827-8151  
Email: [rahul.thakar@nih.gov](mailto:rahul.thakar@nih.gov)

**LUNG DISEASES AND SLEEP AND CIRCADIAN BIOLOGY**

Lei Xiao, M.D., Ph.D.  
Division of Lung Diseases  
Restrictive and Vascular Lung Diseases Branch  
Phone: 301-827-7852  
Email: [lei.xiao@nih.gov](mailto:lei.xiao@nih.gov)

Sidd Shenoy, Ph.D.  
Division of Lung Diseases  
Acute and Infectious Lung Diseases Branch  
Phone: 301-827-4751  
Email: [sidd.shenoy@nih.gov](mailto:sidd.shenoy@nih.gov)

For sleep-related proposals, please contact:

Shilpy Dixit, Ph.D. Division of Lung Diseases  
National Center for Sleep Disorders Research  
Phone: 301-402-9064  
Email: [shilpy.dixit@nih.gov](mailto:shilpy.dixit@nih.gov)

**BLOOD DISEASES AND RESOURCES**

Ron Warren, Ph.D.  
Division of Blood Diseases and Resources  
Translational Blood Science and Resources Branch  
Phone: 301-827-8288  
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Ilana Goldberg, Ph.D.  
Division of Blood Diseases and Resources  
Molecular, Cellular & Systems Blood Science  
Branch Phone: 301-496-8587  
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**CENTER FOR TRANSLATION RESEARCH AND IMPLEMENTATION SCIENCE**

Karen Plevock Haase, Ph.D.  
Center for Translation Research and Implementation Science  
Implementation Science Branch  
Phone: 301-435-6820  
Email: [karen.plevock@nih.gov](mailto:karen.plevock@nih.gov)

# NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

## Mission

The National Human Genome Research Institute (NHGRI) has been guided, since the inception of the Human Genome Project in 1990, by a sequential series of plans, each of which has been developed with considerable input from the scientific community. These plans have always laid out ambitious goals and measurable objectives to gauge progress. The Institute recently examined the current state of genomics and gathered input on its future directions, which resulted in a 2020 strategic plan to guide NHGRI and research at the forefront of genomics (Green *et al.* [Strategic vision for improving human health at The Forefront of Genomics](#). *Nature* 586, 683–692 (2020).

## Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#), unless the application fits an SBA-approved NHGRI waiver topic. For topics listed in the [SBA-Approved Waiver Topics](#), the NHGRI generally will not fund Phase I applications to the Omnibus greater than \$400,000 total costs or Phase II applications greater than \$2,150,000 total costs (not including the costs of [technical and business assistance](#)). For budgetary, administrative, or programmatic reasons, the NHGRI may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. **Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.**

## Specific SBIR and STTR Program Information

Information about the [NHGRI Small Business Program](#) and specific funding announcements is available online. Applicants are strongly encouraged to discuss their research plans with NHGRI Program Staff prior to submitting their applications.

## Clinical Research Support

The National Human Genome Research Institute (NHGRI) will accept applications designated as clinical trials for all program areas supported by the Institute as outlined below for non-clinical trials small business grants. The broadened definition of clinical trials as defined in [NOT-OD-15-015](#) and on the [NIH website](#) is not intended to expand the scope of applications accepted by NHGRI beyond studies that have a major genomic or Ethical, Legal and Social Implications (ELSI) component and relate clearly to NHGRI's mission. Information on areas of research interest is available on the [NHGRI Research Funding Divisions homepage](#) and the [ELSI Research Domains website](#).

## Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NHGRI does not accept applications for Phase IIB competing renewal awards through this Omnibus solicitation. NHGRI participates in the [CRP program](#).

## **Clinical Trials**

Does NHGRI accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NHGRI accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does NHGRI support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	

## **Research Topics**

### **A. Technology and Methods Development**

Technology development in DNA sequencing, genotyping, and single-cell analysis are examples of activities that have changed the nature of what scientific research questions are practical to address, have enabled new approaches, and have facilitated the development of new community resource data sets. Many areas of critical importance to the realization of the genomics-based vision for biomedical research require continued technological and methodological developments before pilots and then large-scale approaches can be attempted. Accordingly, the NHGRI will continue to support the development of new, fundamental technologies in all areas of genomics. Important areas in which technology development applications would be responsive include (but are not limited to) experimental technologies and computational methods to analyze gene expression and other molecular phenotypes; discovery and characterization of genetic variation; identification of the genetic contributions to health, disease, and drug response; statistical analytic methods for understanding human genomic variation and its relationship to health and disease; and chemical genomics. There is also continued need to support technology development for the comprehensive discovery of functional elements in the human and model organism genomes and new nucleic acid sequencing technology. Many of these assays would benefit from the ability to work with very small amounts of starting material down to the level of single cells and subcellular compartments, along with minimally invasive human specimens that are easy to collect, handle, and store. As these technologies mature, emphasis should be on high throughput, cost-effective methods that consistently produce very high- quality data.

The Institute also places high priority on contributing selectively to the development of new and needed technology in related areas, such as proteomics and systems biology research, when NHGRI funding can be used to further a truly unique development that will have a significant impact on the field.

Further information on opportunities related to technology and methods development is available on the [NHGRI Genome Technology Program](#) website.

### **B. Bioinformatics, Computational Genomics, and Data Science**

The ongoing development of new sequencing technologies has dramatically increased the amount of data produced for genomics in basic science and translation to medicine. NHGRI encourages new computational approaches for the analysis, visualization, and integration of genomic information in basic and clinical research and in applications to improve its utility in healthcare. These approaches may include the development of methods for processing,

annotating, interpreting, analyzing, and sharing of sequencing data with associated phenotypes and other large-scale genomic data sets such as haplotype maps, genetic variants, transcriptome measurements, functional elements, and, in some cases, protein interactions. New tools for population-based analysis using the pangenome reference are of interest. NHGRI also encourages the development of better computational solutions for storage, access, compression, secure sharing, privacy, and transfer of large genomic datasets by biomedical researchers.

NHGRI will support projects to improve informatics tools to make them more easily adopted by any biomedical research laboratory that wishes to use genomic technologies to address biomedical questions. This may include making them more efficient, reliable, robust, well-documented, and well-supported, or deploying them in containers or at scale in a cloud-based platform.

Where possible, existing or emerging community data standards, models, and methods for data representation and exchange should be used in the development of these new methods and tools as well as other approaches to enhance reproducibility. Standards-based approaches such as [GA4GH](#) are also encouraged to integrate and share genomics and phenotype data for data mining with other sources including for clinical application. Projects that will make genomic digital objects Findable, Accessible, Interoperable, Reusable (FAIR) in the broader community are highly recommended.

Further information on programs related to NHGRI supported research in these areas is available on the [Computational Genomics and Data Science Program](#) website.

### **C. Population Genomics and Genomic Medicine**

Advances in the understanding of genomic variation across human populations and the functional consequences of variants independently, in combination, and in different environmental contexts have significantly impacted how genomic information can be used in both public health and clinical practice settings, alternatively known as genomic medicine. An existing challenge is how to capture, interpret, and return genomic information at high volumes and in a cost-effective manner. Innovative technologies and methods are needed to allow information on genomic variation to be used broadly in clinical settings while meeting regulatory requirements, to inform public health efforts, and to accurately convey genomic risk profiles to a lay audience.

Biotechnology and informatics have enhanced our ability to survey the entire genome within and among populations. This progress has allowed for improved inferences about evolution of the genome and better characterization of populations, key elements of populations genomics. An existing challenge is how to assemble and analyze multiple genomes using computational methods to identify patterns of genomic divergence. Technology is needed to enable nuanced incorporation of population-based discovery with detailed investigation of disease-based cohorts and prospective variant evaluation. Population genomic information can be used to understand disease process, improve risk prediction, and apply the results in patient care.

The research scope of Population Genomics and Genomic Medicine at NHGRI includes: characterizing the spectrum and distribution of genetic variation in humans and other biomedically relevant organisms; developing statistical and computational methods for comparing genomes and genome function within and across species as well as for relating genetic variation to health- and disease-related traits; developing resources and statistical methods for observational studies and clinical trials incorporating advanced genomic technologies; conducting proof-of-principle studies that apply genomic technologies to epidemiologic and clinical research; developing research methods and infrastructure needed for future epidemiologic and clinical studies of genetic and environmental contribution to disease; investigations of whether and how clinical

genome variation impacts disease prevention diagnosis, and treatment; studies of approaches to improve the identification and interpretation of genomic variation for dissemination in clinical settings; assessing phenotypic manifestations of genetic variation through electronic medical records (EMRs); integrating genomic results and clinical decision support into EMRs; studies that address current barriers to the implementation of clinical genome sequencing; and assessing the impact of genetic information on clinical utility, health outcomes, and delivery of care.

For additional information about Genomic Medicine at NHGRI, please visit the [Division of Genomic Medicine](#) website.

#### **D. Ethical, Legal and Social Implications**

NHGRI, through the ELSI Research Program, supports research studies that examine and address the ethical, legal, and social implications of genomics. These studies may focus on issues associated with genomic research, genomic healthcare, the interplay between the field of genomics and organizations, institutions, or other organized stakeholders, and broader values and societal effects that shape and are shaped by genomics.

More detailed information on specific ELSI research priorities within each of these broad areas is available on the [ELSI Research priorities](#) website.

#### **E. Genomic training and education**

NHGRI supports educational activities and curriculum development that increase genomics knowledge of students, trainees, and genomics professionals. The goal of these activities is to provide an avenue for entry and pursuit of genomics careers. The widespread impact of genomics creates a need to train diverse groups of people to develop innovative and impactful genomic research approaches and resources. Training opportunities may be proposed at the undergraduate, postbaccalaureate, graduate, postdoctoral, or professional level.

For more information on genomic training and education at NHGRI, please visit the [Training Program](#) website.

#### **Contact Information**

For more information on research topics, contact:

Ian Nova, Ph.D.  
Small Business Program Co-Lead (SBIR)  
Phone: 240-987-2885  
Email: [ian.nova@nih.gov](mailto:ian.nova@nih.gov)

Renee Rider, M.S., J.D., LCGC  
Small Business Program Co-Lead (STTR)  
Phone: 301-443-4336  
Email: [renee.rider@nih.gov](mailto:renee.rider@nih.gov)

## NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

### Mission

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Mental disorders constitute an immense burden on the U.S. population, with suicide as one of the leading causes of death in the US, major depression the leading cause of disability in the U.S., and schizophrenia, bipolar disorder, and obsessive-compulsive disorder ranked among the ten leading causes of disability. NIMH also takes a leading role in understanding the impact of behavior on HIV transmission and pathogenesis, and in developing effective behavioral preventive interventions. The NIMH conducts a wide range of research, research training, research capacity development, as well as public information outreach and dissemination to fulfill its mission. The NIMH Strategic Plan (<http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>) and the National Advisory Mental Health Council's workgroup report "From Discovery to Cure" ([http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure\\_103739.pdf](http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure_103739.pdf)) present key scientific priorities across these domains, and describe the need for technologies to realize these priorities. Research priorities for the NIMH further include aspects of HIV/AIDS prevention, treatment, and care, in accordance with the Trans-NIH Plan for HIV-Related Research (<https://www.oar.nih.gov/hiv-policy-and-research/strategic-plan>).

For the Institute to continue fulfilling this vital public health mission, it must foster innovative thinking and ensure that a full array of novel scientific perspectives is used to further discovery in the evolving science of brain, behavior, and experience. In this way, breakthroughs in science can become breakthroughs for all people with mental illnesses.

The NIMH SBIR/STTR programs support small businesses to develop technologies that can advance the mission of the Institute, including in basic neuroscience research relevant to mental disorders, translational and clinical research of mental disorders, clinical diagnosis or treatment of mental disorders, and dissemination of evidence-based mental health care.

For additional information about areas of interest to the NIMH, please visit our home page at <http://www.nimh.nih.gov> and the NIMH SBIR/STTR program priorities page at <https://www.nimh.nih.gov/funding/sbir/nimh-sbir-sttr-program-priorities.shtml>. NIMH has released a notice of considerations regarding the use of animal neurobehavioral approaches, please see NOT-MH-19-053: <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-053.html>. NIMH has specific requirements for clinical trials, please visit: <https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>. A [2020 NAMHC Workgroup on Drug Development](#) provides further guidance on pharmacologic trial designs.

NIMH has additional guidance on areas of interest in stress biology research, please see NOT-MH-18-058: <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-18-058.html>. NIMH has released a notice of considerations for preclinical research involving psychedelics and related compounds: <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-125.html>. The NIMH SBIR/STTR programs will only consider preclinical psychedelics and/or related compound projects.

The NIMH SBIR/STTR website provides guidance and resources for applicants: <https://www.nimh.nih.gov/funding/sbir/>.



## **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). NIH has received a waiver from the SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NIMH that can be found in the [SBA-Approved Waiver Topics](#). Please note, for budgetary, administrative, or programmatic reasons, the NIMH may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

**Applicants with budget questions or considering requesting a budget greater than the SBA defined amounts are strongly encouraged to contact program staff before submitting an application.**

## **Specific SBIR and STTR Program Information**

1. Potential SBIR/STTR applicants should contact NIMH prior to submitting an application to ensure the application is of priority/interest to NIMH. Please see the Contacts section.
2. An additional criterion that the federal government considers in supporting a small business with SBIR/STTR funds, is past commercialization performance. It is expected that small businesses who have received previous SBIR/STTR grants, have had success in commercializing their previously supported technologies. Small businesses that are mostly interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR/STTR program. Program staff at NIMH can help identify the most appropriate grant mechanism to use.

## **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

The NIMH will accept Phase IIB SBIR/STTR Competing Renewal grant applications in two categories: 1) to continue research and development of technologies that ultimately require federal regulatory approval, and 2) to continue research and development of complex instrumentation, clinical research tools, or behavioral/digital health interventions and treatments.

Technologies in the former category (those that ultimately require federal regulatory approval) include but are not limited to pharmacologic agents and drugs, biological products, medical devices, vaccines, etc. related to the mission of the NIMH. Phase IIB SBIR/STTR Competing Renewal grants for such technologies should allow small businesses to move research and development to a stage where interest and investment by third parties is more likely.

Companies that are developing technologies that do not focus on drug development, but that require federal regulatory approval prior to commercialization, may be eligible to submit a Phase IIB Competing Renewal application.

For both technology areas, Phase IIB applications may be submitted through the Omnibus SBIR/STTR Notice of Funding Opportunity. Generally, for this opportunity, budget limits of \$3 million total costs and time periods up to 3 years may be requested. These budget allowances have been approved by the SBA through a waiver. For budgets higher than \$3 million, contact NIMH program staff prior to submitting the application.

The following examples would make appropriate topics for proposed NIMH SBIR/STTR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43/R41) and initial Phase II (R44/R42) grants. Some *in vivo* or *in vitro* studies would be expected to have been carried out in Phase I or the initial Phase II grant.

- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Safety and effectiveness studies of novel medical devices.
- Evaluation of novel imaging approaches for diagnostic purposes.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Although technologies in the latter category listed above (complex instrumentation, clinical research tools, or behavioral interventions/treatments) may not require federal regulatory approval, extraordinary time and effort is needed for their research and development. Therefore, NIMH supports Phase IIB Competing Renewal awards of existing Phase II grants for such technologies. The Phase IIB Competing Renewal award for these would provide up to an additional three years of support at total cost funding levels of up to \$3 million (generally) for the project. These budget allowances have been approved by the SBA through a waiver.

Please contact the Program Director in the appropriate Division or Dr. Margaret Grabb (listed below) before beginning the process of putting an application together. In addition, prospective applicants are encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Notice of Funding Opportunity (e.g., [PA-19-273](#)).

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIMH SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

### **Clinical Trials**

Does NIMH accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	NIMH will prioritize funding for SBIR/STTR applications with a clinical trial focus that are consistent with the stated research goals and priorities relevant to clinical trials as outlined in the clinical trials NOFOs. For more information see: <a href="https://www.nimh.nih.gov/funding/sbir/sbir-amp-sttr-funding-opportunity-announcements">https://www.nimh.nih.gov/funding/sbir/sbir-amp-sttr-funding-opportunity-announcements</a>
Does NIMH accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	NIMH will prioritize funding for SBIR/STTR applications with a clinical trial focus that are consistent with the stated research goals and priorities relevant to clinical trials as outlined in the clinical trials NOFOs. For more information see: <a href="https://www.nimh.nih.gov/funding/sbir/sbir-amp-sttr-funding-opportunity-announcements">https://www.nimh.nih.gov/funding/sbir/sbir-amp-sttr-funding-opportunity-announcements</a>

Does NIMH support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<p>NIMH will prioritize funding for SBIR/STTR applications with a clinical trial focus that are consistent with the stated research goals and priorities relevant to clinical trials as outlined in the clinical trials NOFOs.</p> <p>For more information see: <a href="https://www.nimh.nih.gov/funding/sbir/sbir-amp-sttr-funding-opportunity-announcements">https://www.nimh.nih.gov/funding/sbir/sbir-amp-sttr-funding-opportunity-announcements</a></p> <p>And:</p> <ul style="list-style-type: none"> <li>• First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders (U01 Clinical Trial Required) <a href="#">PAR-21-133</a></li> <li>• Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders (R61/R33- Clinical Trial Required) <a href="#">PAR-21-137</a></li> <li>• Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders (R33- Clinical Trial Required) <a href="#">PAR-21-136</a></li> <li>• Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R61/R33- Clinical Trial Required) <a href="#">PAR-21-135</a></li> <li>• Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders (R33 Clinical Trial Required) <a href="#">PAR-21-134</a></li> <li>• Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders (R01 Clinical Trial Required) <a href="#">PAR-21-132</a></li> <li>• Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions (R34- Clinical Trial Required) <a href="#">PAR-21-131</a></li> <li>• Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (R01 Clinical Trial Required) <a href="#">PAR-21-130</a></li> <li>• Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions (Collaborative R01 - Clinical Trial Required) <a href="#">PAR-21-129</a></li> </ul>
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## **Research Topics**

### **Division of Neuroscience and Basic Behavioral Science (DNBBS)**

The Division of Neuroscience and Basic Behavioral Science provides support for research programs in the areas of basic neuroscience, genetics, basic behavioral science, research training, resource development, technology development, drug discovery, and research dissemination. The Division has the responsibility, in cooperation with other components of the Institute and the research community, for ensuring that relevant basic science knowledge is generated and then harvested to create improved diagnosis, treatment, and prevention of mental and behavioral disorders.

In this Division, the SBIR and STTR programs support research and the development of tools related to basic brain and behavioral science, genetics, and drug discovery and development relevant to the mission of the NIMH. Such tools include software (such as informatics tools and resources and tools for analyzing data); hardware (such as the development of instrumentation or devices); wetware (such as the use of iRNAs or other bioactive agents as research tools or molecular imaging agents or genetic approaches to label neural circuits or modify circuit functions); and drug discovery related technologies such as high throughput screening (HTS) or computational pharmacology approaches. Assay development projects should follow the best practices laid out in the Assay Guidance Manual: <https://www.ncbi.nlm.nih.gov/books/NBK53196/>.

#### **AREAS OF EMPHASIS**

- Novel imaging probes to study brain structure and function at all levels, from the molecular level to the whole organ, using any imaging modality (PET, fMRI, optical, etc.) in animal or human studies.
- Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.
- First in human drug trials.
- Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to behavior.
- Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders, using animals or when applied to humans.
- Develop informatics tools to facilitate the analysis and sharing of data between laboratories about behavior and the brain. This could include common data element efforts but is not limited to that area.
- Technologies consistent with the goals of the BRAIN Initiative: <http://www.braininitiative.nih.gov/>, including human/ clinical-based technologies.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb and Ms. Paige Anderson (listed below) with questions about the relevance of their interests to the mission of this division.

#### **Division of Translational Research (DTR)**

The DTR directs, plans, and supports programs of research and research training that translate knowledge from basic science to discover the etiology, pathophysiology, and trajectory of mental disorders and develops effective interventions for children and adults. DTR supports integrative, multidisciplinary research on the following areas: the phenotypic characterization and risk factors for psychiatric disorders; neurobehavioral mechanisms of psychopathology; trajectories of risk and resilience based on the interactive influences of genetics, brain development, environment, and experience; and design and testing of innovative psychosocial, psychopharmacologic, and somatic treatment interventions.

In this Division, the SBIR and STTR Programs support research aimed at facilitating the validation and commercialization of new methods of assessing psychopathology and measuring treatment

response to therapeutic agents. In addition, the SBIR and STTR Programs support the clinical development of interventions, including novel pharmacologic agents or brain stimulation devices as well as technology development used to deliver novel psychosocial approaches to the treatment of mental illness in adults, pediatrics and geriatrics. For more information on NIMH supported clinical trials and requirements, see: <https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>

#### **AREAS OF EMPHASIS**

- Develop valid measures of the various constructs in the Research Domain Criteria (RDoC) matrix (see <https://www.nimh.nih.gov/research/research-funded-by-nimh/rdoc/index.shtml>), e.g., behavioral tasks, psychometrically sophisticated self-report measures, and measures of physiological and neural activity, into a commercial product.
- Conduct early stage, proof of concept clinical trials to advance the development of novel therapeutics. The clinical trials are expected to include biological/behavioral data to assess target engagement and to help determine potential success or failure of the compound before moving on to larger clinical trials (see NOT-MH-11-015 <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html>).
- Develop, test and perform initial validation of reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis and classification, predict treatment response, or to measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects. Biomarkers in psychiatry will initially be appropriate as clinical research tools, and only after significant technical and clinical validation, could move toward diagnostic utility or other context of uses.
- Development of novel diagnostic tools and innovative measures of treatment response and disease progression, preclinical or clinical efficacy testing, or toxicity measures for drug development.
- Development of hardware and software tools to enable refined physiological and behavioral assessment of normal and atypical neurodevelopment focused on pediatrics, adult and geriatric age ranges.
- Web-based tools and biosensors to enhance prevention, early identification and treatment of pediatric mental disorders by various educational and health professionals.
- Development of hardware and software tools to support operations of multi-site clinical trials.
- Development of novel methods to enhance efficiency of early phase clinical trials.
- Novel technologies and data analytic tools to enable quantification of behavioral data that is relevant to research or clinical trials in mental disorders and/or autism.
- Development of imaging technologies that can reveal specific pathologies in major mental disorders.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

#### **Division of AIDS Research (DAR)**

The NIMH DAR supports scientific research to understand and alleviate the consequences of HIV

disease on the central nervous system, and research to strengthen the provision and outcomes of HIV/AIDS prevention and treatment. Examples of high-priority research areas for SBIR/STTR applications are described below.

- Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to comprehend HIV-1 associated CNS dysfunction and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS.
- Design and test novel therapeutic interventions aimed at amelioration of HIV-1 associated CNS dysfunction, and/or eradication of HIV-1 from CNS reservoirs, and/or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.
- Tools to assess neurotoxicity profiles of antiretroviral medications and pharmacological strategies to reduce adverse effects of anti-retroviral drugs (neuropsychiatric side effects and drug-drug interactions).
- Develop new tools/ techniques to aid in deciphering the complex neuro-immune interactions at a molecular and cellular level in the context of HIV.
- Develop or adapt neurological/neuropsychological/neurobehavioral assessments to evaluate HIV-1 associated abnormalities in adults or children in resource limited environments that are adaptable to different cultures and languages.
- Build and optimize informatics tools to aid in analyzing and characterizing the phenotype of CNS disease modalities associated with HIV by using machine learning, big data and systems biology- based approaches.
- Develop technologies and tools to increase regular HIV testing and support uptake, adherence, and persistence to biomedical HIV prevention regimens among persons behaviorally vulnerable to HIV or to biomedical HIV treatment regimens among people newly diagnosed with HIV.
- Develop innovative tools and approaches that use existing patient-level data, such as electronic medical records and prescription refill or claim data, to improve engagement in HIV care or HIV treatment adherence to strengthen sustained viral suppression, including development and testing of predictive algorithms to identify those at risk for future non-adherence.
- Develop approaches that seamlessly integrate tools for mental health screening and treatment into HIV healthcare or increase the capacity of HIV clinics to address mental health concerns.
- Develop decision support tools that help individuals, couples, and clinicians make informed choices about the increasing number of proven and available HIV prevention and treatment regimens, including long-acting regimens and multipurpose prevention technologies (MPTs).
- Develop innovative wireless technologies, remote sensing devices, biomarkers, assays, or other novel methods to improve scientific measurement of HIV exposure due to sexual behavior, or scientific measurement of social determinants that influence HIV treatment and prevention. Assessment approaches could occur retrospectively (not a clinical trial – using existing data, such as electronic medical records).
- Develop and improve digital communication technologies to raise HIV awareness and

promote accurate and timely health information to users, groups, and geographic regions most impacted by HIV.

- Develop and test tools, curricula, and strategies that seek to reduce documented HIV-related disparities and health inequities (e.g., age, sex, gender identity, sexual orientation, race, ethnicity, socioeconomic circumstance, etc.) in HIV incidence and HIV prevention, treatment, and cure outcomes.
- Develop innovative long-acting systemic and non-systemic multipurpose prevention technologies that prevent HIV infection and pregnancy (hormonal and non-hormonal methods) in adolescents and young women.

Prospective applicants are strongly encouraged to contact Dr. Vasudev R Rao (listed below) with questions about the relevance of their interests to the mission of this division.

### **Division of Services and Intervention Research (DSIR)**

The Division of Services and Intervention Research (DSIR) SBIR/STTR supports two critical areas of research for people with or at risk for mental illness:

- Intervention research to evaluate the efficacy and effectiveness of pharmacologic, psychosocial, somatic, rehabilitative, sequential and combination interventions on mental and behavior disorders- including acute and longer-term therapeutic effects on functioning across domains for children, adolescents, and adults.
- Mental health services research to improve the access, continuity, equity, value, quality and outcomes of mental health care, as well as to improve the dissemination of information about and the implementation of effective interventions, to strengthen the public health impact of NIMH research.

The intervention research program aligns with [NIMH Strategic Objectives 3.2 and 3.3](#) and addresses the efficacy/effectiveness of treatment and preventive interventions in usual practice and community settings with the purpose of informing clinicians, patients, families, and health policy makers on evidence-based practices. In funding decisions, special emphasis is placed on the potential clinical and/or public health impact of the research activities and on the implications of the research findings for improving community practice and health outcomes. Types of interventions include the full range of behavioral, psychotherapeutic, pharmacologic, and non-pharmacologic somatic or complementary/alternative interventions, as well as rehabilitation or other adjunctive services, e.g., integrated approaches to chronic mental illness. Examples of areas of interest are:

- Analyses of naturalistic databases to evaluate the effectiveness of preventive and treatment interventions.
- Randomized clinical trials evaluating the effectiveness of preventive and treatment interventions that have been augmented or refined with the intent to enhance their clinical potency or efficiency.
- Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions.
  - Moderator/mediator identification could occur retrospectively (not a clinical trial – using EHR).
  - Moderator/mediator identification could occur prospectively (within the context of a clinical trial).
- Evaluating the effectiveness of predictive algorithms to improve identification and intervention of individuals at elevated risk of mental illness and suicide.

- Evaluating the combined or sequential use of interventions.
  - Evaluation of combined/sequential interventions could occur retrospectively (not a clinical trial – using EHR).
  - Evaluation of combined/sequential interventions could occur prospectively (within the context of a clinical trial).
- Determining the optimal duration, frequency and intensity of an intervention to optimize improvements in symptoms and functioning, establishing the utility of preventive intervention or continuation or maintenance treatment (that is, for prevention of relapse or recurrence).
  - Evaluation of the optimal length of an intervention could occur retrospectively (not a clinical trial – using EHR).
  - Evaluation of the optimal length of an intervention could occur prospectively (within the context of a clinical trial).
  - Evaluating the long-term impact of preventive and therapeutic interventions on symptoms, functioning, and quality of life.
  - Evaluation of the optimal length of an intervention could occur retrospectively (not a clinical trial) – using EHR or survey data).
  - Evaluation of the optimal length of an intervention could occur prospectively (within the context of a clinical trial).

Services research covers all mental health services across the lifespan for all mental health disorders, includes clinical trial and non-clinical trial designs, and aligns with [NIMH Strategic Objective 4](#) , which includes but is not limited to:

- Service settings at the patient, provider, health system, and cross system levels to include primary care, specialty mental health, emergency departments, integrated care, general medical, and other delivery settings (such as employment, educational, veteran, military, criminal justice, child welfare, juvenile justice and other community settings).
- Enhanced capacity for conducting services research by developing and utilizing innovative and established methodologies, including health economics, to inform decisions about the organization, delivery and financing of care.
- The clinical epidemiology of mental disorders to include development and use of data sets from health surveillance activities, decision support tools, administrative claims, mobile apps and similar technologies, electronic health record (EHR), disease registries, and other databases where epidemiological data (to include big data) reside.
- Interventions and other research to improve access, continuity, engagement, quality, uptake, equity, efficiency, and cost of care.
- Research that reduces disparities and advances equity in mental health interventions, services, and outcomes for racial and ethnic minority groups, individuals limited by language or cultural barriers, sexual and gender minorities, individuals living in rural areas, socioeconomically disadvantaged persons and other underserved groups.
- The dissemination of information about and implementation of evidence-based interventions, programs, support tools, or other practices or technologies into service settings.



For both interventions and services research, DSIR supports the development and testing of digital health tools. These tools include technology-assisted approaches to assessment (e.g., technology-assisted screening and diagnosis) and intervention (e.g., m-health and other technology platforms to support the delivery of preventive, therapeutic, and services interventions). DSIR encourages efforts to employ technology-assisted approaches to expand the reach, efficiency, continuity, quality, and/or boost the therapeutic benefit of research-informed strategies, rather than mere translation of research-supported strategies onto new or emerging technology platforms. Collaboration with NIMH-supported researchers for the development of software for new analytic techniques and/or decision-making algorithms is encouraged. Also supported is research and the development or adaptation of tools and technologies to be used to enhance the training and development of new generations of researchers and practitioners and to keep established researchers and practitioners up-to-date on the findings, implementation, and methods of interventions and services research.

Prospective applicants are strongly encouraged to contact Dr. Adam Haim (listed below) with questions about the relevance of their interests to the mission of this division.

### **Contact Information**

Margaret Grabb, Ph.D. (general questions about the NIMH SBIR program, Phase IIB program, DNBBBS, DTR divisional interests)  
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# NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

## Mission

The mission of the National Institute on Minority Health and Health Disparities (NIMHD) is to promote minority health and to lead, coordinate, support, and assess the National Institutes of Health (NIH) efforts to improve minority health and reduce and ultimately eliminate health disparities. In this effort, the NIMHD conducts and supports basic, clinical, social and behavioral research; facilitates the development of research infrastructure and training; fosters emerging programs; and reaches out to racial/ethnic minority populations and other U.S. populations with health disparities, defined in section 464z-3(d)(1) of the Public Health Service Act, 42 U.S.C. 285t(d)(1) as “health disparity populations” based on higher overall rates of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the health status of the general population. NIH-designated U.S. health disparity populations currently include Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities.

## Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). For budgetary, administrative, or programmatic reasons, the NIMHD may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NIMHD that can be found in the [SBA-Approved Waiver Topics](#). **Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.**

## Specific SBIR and STTR Program Information

The Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program enable the Nation’s small businesses to apply their unique research and development capabilities toward accomplishing NIMHD’s mission. NIMHD has developed a research framework and small businesses are encouraged to consider the factors operating within and across the frameworks’ multiple ecosocial levels and domains before initiating the design of products for potential research and development by NIMHD (see the [NIMHD Research Framework](#) for more information). The framework, initially developed for researchers, can also inform small businesses’ research and development of new technologies, products, and services for improving, sustaining or enhancing minority health and extending longevity and for reducing or eliminating health disparities. The factors identified in the framework are known to contribute to the creation and perpetuation of poor minority health and health disparities over time and place. Entrepreneurs are encouraged to consider these and other factors when conceptualizing, designing, and prototyping novel products seeking NIMHD SBIR and STTR funding. Minority health and health disparity academic researchers are encouraged to consider partnering with small businesses to assist in translating NIMHD- or NIH-funded research findings into potentially commercializable products for improving minority health or eliminating health disparities within one or more levels or domains of influence.

Through small business Phase I, Phase II, and Fast-track awards, NIMHD supports multi- and trans-disciplinary research and development leading to novel and or improved products capable of contributing to NIMHD’s mission. Research and development informed by the NIMHD Research

Framework or other framework may proceed or be initiated at the molecular, cellular, individual, community or population level. Funding support for focus groups, phase I/II clinical trials, and other studies involving human participants needed to develop and test the proposed product may be requested. Additionally, NIMHD seeks innovative strategies for improving minority health, eliminating health disparities, and enhancing health and well-being where small businesses engage, collaborate or partner with health disparity communities from conception, application submission, and through completion of NIMHD funding periods and beyond. The NIMHD Research Framework acknowledges the value of small businesses partnering with community-based or -located organizations or small businesses and with health care providers and health care-organizations. Applications partnering with community health centers or other patient providers are encouraged and of interest. Applications developing innovative technologies or services for enhancing minority health and well-being through partnerships with community-based small businesses, such as beauty salons, barbershops, pharmacies, etc., that engage with racial and ethnic minority or health disparity populations on a regular basis, are also of interest.

Technology that leverages indigenous community advisors and supporters in health promotion or prevention efforts may contribute to overall community health improvement and well-being through the processes of community empowerment and increased community cohesion.

An overarching objective of NIMHD’s investments in SBIR/STTR programs is to ensure that racial and ethnic minorities and health disparity populations benefit equally from innovations in health promotion, educational and medical curricula, prevention interventions, biotechnology, imaging technologies, technologies for computational biology and informatics, including, for example, systems and structural biology; and technologies designed to advance personalized medicine and health, electronic health records, and systems, etc. New or improved instruments, devices, and related methodologies to facilitate biomedical or behavioral research and efforts that seek to simplify via redesign or the design of new instruments, devices, and methods likely to increase access, reduce costs, and improve quality of care and outcomes are of special interest.

**Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NIMHD welcomes Phase IIB Competing Renewal Applications for Phase II grants and contracts via the Omnibus Solicitation for SBIR or STTR Grant Applications, and as indicated by other NIMHD Notices of Funding Opportunities (NOFOs). Standard NIMHD Phase II funding policy applies unless otherwise stated in the NOFO. Non-NIMHD Phase II awardees must contact NIMHD prior to submission to confirm programmatic interest.

**Clinical Trials**

Does NIMHD accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NIMHD accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	<a href="https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities">https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities</a>
Does NIMHD support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	

**Research Topics**

Applicants are encouraged to engage in research and development that results in a product,

process or service that will improve minority health and eliminate health disparities and that by design targets or involves any of the topics listed in the NIMHD waiver list or otherwise will contribute to the NIMHD mission. For additional information about research areas of interest to the NIMHD, please visit our website at <https://www.nimhd.nih.gov/programs/extramural/research-areas/>.

### **Contact Information**

For additional information on research topics, contact:

#### **Division of Community Health and Population Science**

LCDR Michael Banyas, USPHS,

M.P.A, M.A, Program Manager

National Institute on Minority Health and Health

Disparities, NIH Email: [michael.banyas@nih.gov](mailto:michael.banyas@nih.gov)

Phone: 301-827-7478

# NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

## **Mission**

The mission of NINDS is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world (<https://www.ninds.nih.gov/About-NINDS/Who-We-Are/Mission>). To this end, the Institute supports and conducts research on the healthy and diseased brain, spinal cord, and peripheral nerves. The NINDS SBIR/STTR (<https://www.ninds.nih.gov/Funding/Small-Business-Grants>) program funds small business concerns to conduct innovative neuroscience research and/or development (R/R&D) that has both the potential for commercialization and public benefit.

## **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#), unless the application fits an SBA-approved waiver topic. For topics listed in the [SBA-Approved Waiver Topics](#), NINDS generally will not fund Phase I applications to the Omnibus greater than \$700,000 total costs, with no more than \$500,000 total cost in an year or project periods greater than 2 years; or Phase II applications greater than \$3,000,000 total costs, with no more than \$1,500,000 or project periods greater than 3 years. For budgetary, administrative, or programmatic reasons, the NINDS may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Information about the NINDS budget guidelines can be found on the NINDS SBIR webpage <https://www.ninds.nih.gov/funding/ninds-small-business-program/submitting-small-business-application>.

For all other funding opportunities, applications should follow the guidelines in the Award Budget section of those announcements carefully.

All applicants are strongly encouraged to contact program staff before submitting an application.

## **Specific SBIR and STTR Program Information**

### **NINDS Priorities**

NINDS priorities are given to meritorious research proposals with the greatest potential to advance the NINDS mission (see <https://www.ninds.nih.gov/About-NINDS/Who-We-Are/Mission>). NINDS is especially interested in:

1. Novel and innovative technologies that are new to the SBIR or STTR programs.
2. Technologies coming to the SBIR or STTR programs for their first indication or market opportunity.
3. Companies and applicants that are new to the SBIR and STTR programs.
4. NINDS Cooperative Agreement (U44) Translational Programs. NINDS has specific translational programs that utilize the SBIR cooperative agreement mechanism (U44) as noted below. If eligible, companies are encouraged to apply through these programs.

NINDS SBIR and STTR funding decisions are based on a combination of factors:

1. potential for high impact on advancing the NINDS mission and the other programmatic priorities described in NOT-NS-18-002 (<https://grants.nih.gov/grants/guide/notice-files/NOT-NS-18-002.html>);
2. potential for commercialization;
3. portfolio balance (to determine whether similar projects have already been funded, search NIH Reporter <http://projectreporter.nih.gov/reporter.cfm>);
4. the quality of the previous performance of the applicant and/or company in the SBIR and/or STTR program, including evidence of Phase III activities;
5. for Phase II applicants, the results of the Phase I;
6. the peer review scores and critiques; and
7. availability of funds.

### **Research Topics General Areas of Interest**

The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS are shown below. This list is not all inclusive and some research areas fall into multiple categories.

1. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the nervous system.
2. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems
3. Technology and Tools, including technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

More information on NINDS areas of interest for the SBIR and STTR programs can be found here: <https://www.ninds.nih.gov/funding/ninds-small-business-program/ninds-small-business-program-areas-interest>.

### **Clinical Trials**

Does NINDS accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No	
Does NINDS accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	NINDS may accept and support SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NINDS Funding Opportunities webpage: <a href="https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities">https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities</a> .
Does NINDS support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	NINDS accepts and supports SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NINDS Funding Opportunities webpage: <a href="https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities">https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities</a> .

### **NINDS Clinical Trials Topics:**

NINDS is committed to identifying effective treatments for neurological disorders by supporting well-executed clinical trials. NINDS may accept and support SBIR and STTR clinical trial applications within the NINDS mission through specific opportunities. Other human subjects research can be submitted through the SBIR and STTR Parent (Clinical Trials Not Allowed) solicitation. However, NINDS may decline funding of any application that includes human subjects for programmatic or administrative reasons. SBIR applicants considering projects involving human subjects research are strongly encouraged to contact program staff in advance of submission.

### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NINDS only accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NINDS Funding Opportunities webpage: <https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities>. Contact [ninds\\_sbir@ninds.nih.gov](mailto:ninds_sbir@ninds.nih.gov) for additional information.

### **Specific Funding Opportunities and Programs**

#### **NINDS Translational Research Programs**

The NINDS offers a variety of specific funding opportunities and programs to accelerate the preclinical discovery and development of new therapeutic interventions for neurological disorders. These programs have specific funding opportunities and allow for budgets over the hard cap. Several programs utilize the cooperative agreement (U44) mechanism, which is milestone-driven and involves NIH program staff participation in developing the project plan, monitoring research progress, and appropriate go/no-go decision-making. SBIR applicants considering projects involving translational research are strongly encouraged to contact program staff well in advance of submission.

- **Blueprint Neurotherapeutics Network for Biologics (BPN-Biologics)** is dedicated to biotechnology product- and biologics-based therapies, which broadly include modalities such as peptides, proteins, oligonucleotides, gene therapies, and cell therapies. The program supports lead optimization, IND-enabling studies for the candidate, and early-phase clinical trials. Contact: Chris Boshoff ([chris.boshoff@nih.gov](mailto:chris.boshoff@nih.gov))
- **Blueprint MedTech Program** provides support for innovators developing groundbreaking medical device technologies. The mission of the program is to catalyze the translation of novel technologies from early-stage development to readiness for first-in-human clinical studies. Contact: [NINDS-Devices@nih.gov](mailto:NINDS-Devices@nih.gov); [Blueprint-MedTech@nih.gov](mailto:Blueprint-MedTech@nih.gov)
- **Blueprint Neurotherapeutics Network (BPN)** provides both funding and non-dilutive support for small molecule drug discovery and development, from hit-to-lead chemistry through phase I clinical testing. The program offers funding, access to NIH-funded contract research organizations (CROs), and access to consultants with expertise in various aspects of drug discovery and development. Contact: Charles Cywin ([charles.cywin@nih.gov](mailto:charles.cywin@nih.gov))
- **NIH Countermeasures Against Chemical Threats (CounterACT)** supports research to understand the fundamental mechanisms of toxicity caused by chemical threat agents and the development of new and improved therapeutics for reducing mortality and morbidity caused by these agents. Chemical threats are toxic compounds that could be used in a terrorist attack against civilians, or released at

toxic levels by accident, such as from industrial production, storage, or shipping, or natural disaster. NINDS supports partnerships between small business and not-for-profit laboratories engaged in research related to the NIH CounterACT program that falls within the NINDS mission, including devices that could be used during a chemical emergency involving mass casualties, as well as some research on therapeutics. The CounterACT program only supports research on chemical threats that have been identified by the United States Government (USG) as Chemicals of Concern (CoC). There are over 200 CoCs, grouped by primary mechanism of action into toxidromes. The toxidromes that fall under the NINDS mission (with chemical threat examples) are: Anticoagulants (e.g., brodifacoum, bromadiolone, diphacinone), Blood/Metabolic (Knockdown) agents (e.g., hydrogen cyanide, hydrogen sulfide, arsenic trioxide), Cholinergic (Organophosphate Nerve Agents and Insecticides) (e.g., sarin, soman, parathion, phorate, aldicarb), and Convulsants (e.g., picrotoxin, TETS, strychnine). All potential applicants should contact program staff to ensure their chemical threat is of interest to the program. Contact: Shardell Spriggs ([shardell.spriggs@nih.gov](mailto:shardell.spriggs@nih.gov))

- **Office of the Neural Exposome and Toxicology (ONETOX)** supports research on exposures that have an impact on neurological disease and disorders, and overall nervous system health. The exposures described in the exposome not only include environmental chemical and biological toxins, but also psychosocial factors and internal factors such as diet and the microbiome, and these exposures may occur anytime from in utero to late in life. NINDS only support studies within the NIND mission space. Contact: David Jett ([david.jett@nih.gov](mailto:david.jett@nih.gov))
- **Translational Neuroscience Biomarker Program** focuses on improving the quality and efficiency of neurotherapeutic clinical research by supporting rigorous biomarker development and validation. In order to achieve this goal, the program: 1) promotes rigorous biomarker identification and validation through milestone-driven funding opportunities, and 2) facilitates the validation of biomarkers and biomarker signatures as fit for purpose tools for use in clinical trials to accelerate therapeutic development and aid in decision making for patient care. Contact: Carol Taylor-Burds ([carol.taylor-burds@nih.gov](mailto:carol.taylor-burds@nih.gov)).
- **Stroke Preclinical Assessment Network (SPAN)** seeks to conduct late-stage preclinical studies of putative neuroprotectants combined with reperfusion. SPAN utilizes a novel, adaptive, secured system for parallel testing of promising interventions designed to extend the treatment time window and/or improve outcome compared to reperfusion when combined with thrombolysis, thrombectomy or both. Contact: Francesca Bosetti ([frances@mail.nih.gov](mailto:frances@mail.nih.gov))

Information about these and other programs can be found at <https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Translational-Research>.

## Trans-NIH Initiatives

### Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a Presidential project aimed at revolutionizing our understanding of the human brain. NIH is one of several federal agencies involved in the BRAIN Initiative. Planning for the NIH component of the BRAIN Initiative is guided by the long-term scientific plan, "BRAIN 2025: A



Scientific Vision,” which details seven high-priority research areas. This report can be found at <https://braininitiative.nih.gov/>.

NIH has a number of specific Notices of Funding Opportunities through the BRAIN Initiative that are targeted to small business concerns. These funding opportunities can be found at <https://www.braininitiative.nih.gov/funding/>. Applicants are encouraged to consider if these funding opportunities may be appropriate to their research. Contact [ninds\\_sbir@ninds.nih.gov](mailto:ninds_sbir@ninds.nih.gov) for additional information.

### **Helping to End Addiction Long-term (HEAL) Initiative**

The Helping to End Addiction Long-term (HEAL) Initiative is an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. Further information on the HEAL Initiative can be found at <https://heal.nih.gov/>. NIH has several specific Notices of Funding Opportunities through the HEAL Initiative that are targeted to small business concerns. These funding opportunities can be found at <https://heal.nih.gov/funding>. Applicants are encouraged to consider if these funding opportunities may be appropriate to their research. Contact [ninds\\_sbir@ninds.nih.gov](mailto:ninds_sbir@ninds.nih.gov) for additional information.

### **Alzheimer's Disease and Related Dementias (AD/ADRD)**

NINDS collaborates with NIH's National Institute on Aging (NIA), the lead NIH Institute for Alzheimer's disease (AD) research and for NIH's response to the [National Plan to Address Alzheimer's Disease](#), to establish research priorities and fund biomedical research to decrease the burden of dementia on individuals, families, and communities. Learn more about AD/ADRD funding opportunities here: <https://www.ninds.nih.gov/current-research/focus-disorders/focus-alzheimers-disease-and-related-dementias>. Applicants are encouraged to consider if these funding opportunities may be appropriate to their research. Contact [ninds\\_sbir@ninds.nih.gov](mailto:ninds_sbir@ninds.nih.gov) for additional information.

For additional information about NINDS funding opportunities, please visit the NINDS Funding Opportunities webpage at: <https://www.ninds.nih.gov/Funding/Find-Funding-Opportunities>.

### **Contact Information**

#### **Scientific/Research Contact**

Emily Caporello, Ph.D.  
Director, NINDS Small Business Program  
Phone: 301-496-1779  
Email: [emily.caporello@nih.gov](mailto:emily.caporello@nih.gov)  
Program-wide Email: [ninds\\_sbir@ninds.nih.gov](mailto:ninds_sbir@ninds.nih.gov)

#### **Financial/Grants Management Contact:**

Chief Grants Management Officer  
National Institute of Neurological Disorders and Stroke (NINDS)  
Email: [ChiefGrantsManagementOfficer@ninds.nih.gov](mailto:ChiefGrantsManagementOfficer@ninds.nih.gov)

## NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

### **Mission**

The National Institute of Nursing Research (NINR) leads nursing research to solve pressing health challenges and inform practice and policy – optimizing health and advancing health equity into the future.

### **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SBIR website](#). For budgetary, administrative, or programmatic reasons, the NINR may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from the SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NINR that can be found in the [SBA-Approved Waiver Topics](#). The NINR will generally not fund:

- Phase I applications to the Omnibus greater than \$385,000 total costs or project periods greater than 2 years, or
- Phase II applications greater than \$2,500,000 total costs or project periods greater than 3 years.

Applicants that are considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.

### **Specific SBIR and STTR Program Information**

The NINR SBIR program is technology agnostic and welcomes all innovative solutions with commercial potential that are relevant to the NINR mission and research topics listed below.

Technical and Business Assistance (TABAs). NINR will consider well justified TABA costs up to the limits specified on the [NIH SEED Website](#). Applicants can request TABA funding within your award or apply for an NIH TABA program. Applicants cannot receive both.

For additional information about NINR's Small Business Programs, please visit NINR's [Small Business Funding](#).

### **Specific Funding Opportunities and Programs**

NINR will also consider SBIR/STTR application related to other [NINR funding initiatives](#) that is relevant to the Institute's mission. These funding opportunities are revised throughout the year, so please [subscribe](#) to receive regular updates

### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NINR does not accept Phase IIB applications.

NINR does not participate in the Commercialization Readiness Pilot (CRP) Program.

### Clinical Trials

Does NINR accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NINR accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	<a href="https://www.ninr.nih.gov/researchandfunding/fundingopportunities">https://www.ninr.nih.gov/researchandfunding/fundingopportunities</a>
Does NINR support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<a href="https://www.ninr.nih.gov/researchandfunding/fundingopportunities">https://www.ninr.nih.gov/researchandfunding/fundingopportunities</a>

### Research Topics

NINR has developed a [research framework](#) that takes advantage of what makes the Institute unique by focusing on a holistic, contextualized approach to optimizing health for all people, rather than on specific diseases, life stages, or research topics. The framework builds on the strengths of nursing research, spans the intersection of health care and public health, and encompasses the clinical and community settings where nurses engage in prevention, treatment, and care—including hospitals and clinics, schools and workplaces, homes and long-term care facilities, justice settings, and throughout the community. The framework encourages research that informs practice and policy and improves health and quality of life for all people, their families and communities, and the society in which they live. NINR’s research framework includes guiding principles and research lenses that promote innovative and rigorous multilevel study designs that look upstream, midstream, and downstream to discover solutions to the nation’s most pressing and persistent health challenges. NINR’s guiding principles describe the qualities that investigators should emphasize in all NINR-supported research. In considering awards for funding, the extent to which studies reflect these principles will factor into our decisions.

NINR will prioritize research that:

- Tackles today’s pressing health challenges and stimulates discoveries to prepare for, prevent, or address tomorrow’s challenges.
- Discovers solutions across clinical, community, and policy settings to optimize health for individuals, families, communities, and populations.
- Advances equity by removing structural barriers from research, cultivating diversity in perspectives and ideas, and fostering inclusion and accessibility in designing, conducting, and participating in research; and
- Is innovative, develops or applies the most rigorous methods, and has the potential for the greatest impact on health.

NINR identified five complementary and synergistic research lenses that best leverage the strengths of nursing research and promote multilevel approaches, cross-disciplinary and -sectoral collaboration, and community engagement in research. It is important to note that the lenses are not research topics, but rather perspectives through which to consider the full spectrum of nursing research topics that encompass health and illness within the context of people’s lived experiences. These lenses allow nursing research to examine new topics while also allowing scientists to take a different look at long-standing areas of interest. The research lenses are:

- **Health Equity:** Reduce and ultimately eliminate the systemic and structural inequities that place some at an unfair, unjust, and avoidable disadvantage in attaining their full health potential.
- **Social Determinants of Health:** Identify effective approaches to improve health and quality of life by addressing the conditions in which people are born, live, learn, work, play, and age
- **Population and Community Health:** Address critical health challenges at a macro level that persistently affect groups of people with shared characteristics
- **Prevention and Health Promotion:** Prevent disease and promote health through the continuum of prevention – from primordial to tertiary
- **Systems and Models of Care:** Address clinical, organizational, and policy challenges through new systems and models of care

**NINR encourages researchers to view the health equity and social determinants of health lenses as primary foci through which to consider the population and community health, prevention and health promotion, and systems and models of care lenses.**

See [NINR's Strategic Plan](#) for more information on each of the research lenses.

**NINR does not generally support the development of technologies in the following topic areas:**

- Technologies designed for staffing purposes.
- Technologies designed to provide nurse educational and professional training (e.g., VR simulations).
- Technologies that assess or limit exposure to occupational health stressors.
- Technologies for sanitization or decontamination in a clinical setting.

**NINR is particularly interested in applications from socially/economically disadvantaged small businesses (SDB), women-owned small business (WOSB), and small businesses located in under-represented states.** Responsive entrepreneurs should aim to develop technologies that align with the research topics above.

Applicants **do not** need to have a nursing background to apply.

**NINR Clinical Trials Topics:**

NINR accepts clinical trials in any of the topic areas above.

**Contact Information**

For additional information please contact:

Dr. Karen Kehl  
 Director, SmallBusiness Innovation Research Program  
 National Institute of Nursing Research (NINR)  
 Division of Extramural Science Program (DESP)  
 6701 Democracy Blvd, Room 727  
 Bethesda, MD 20892-4870  
 Office: (301) 594-8010  
 Email: [karen.kehl@nih.gov](mailto:karen.kehl@nih.gov)

# **NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)**

## **Mission**

NCATS is transforming translational science to improve human health; it relies on the power of data, new technologies and teamwork to develop, demonstrate and disseminate innovations that reduce, remove or bypass costly and time-consuming bottlenecks in translational research. For additional information please visit the NCATS Strategic Plan webpage -

<https://ncats.nih.gov/strategicplan/introduction>

NCATS small business funding is designed specifically to transform the translational science process so that new treatments and cures for diseases can be delivered to patients more quickly. The Center supports the development of technologies, assays, drugs, devices, instruments, and methodologies that may have broad application to any stage of the translational process from preclinical development to clinical research and to implementation science in patient care and public health. For additional information, please visit <http://www.ncats.nih.gov>.

NCATS is committed to supporting small business Phase I, Phase II, Fast-track and Phase IIB Competing Renewal awards through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Programs (STTR). For additional information, please visit <http://ncats.nih.gov/smallbusiness>.

## **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). For budgetary, administrative, or programmatic reasons, NCATS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

For certain topical areas, there is an [SBA-Approved Waiver Topics](#) list for which the NCATS generally will not fund:

- Phase I applications greater than \$350,000 total costs or project periods greater than 2 years
- Phase II applications greater than \$2,150,000 total costs or project periods greater than 3 years

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

## **Specific SBIR and STTR Program Information**

### **NCATS Clinical Trials Topics**

NCATS will not accept SBIR and STTR applications that propose clinical trials under the Omnibus solicitation.

## **Specific Funding Opportunities and Programs**

There are more than 6,500 identified rare and neglected diseases, yet only about 250 treatments are available for these conditions. The limited numbers of patients can make gathering information and designing drug studies difficult. As a result, scientists often know little about the symptoms and biology of these conditions. Also, some private companies may find it difficult to justify the cost of developing drugs for such small rare disease markets.

The Therapeutics for Rare and Neglected Diseases (TRND) program is designed to combat these challenges. Its mission is to encourage and speed the development of new treatments for diseases with high unmet medical needs. TRND stimulates therapeutic development research collaborations among NIH and academic scientists, nonprofit organizations, and pharmaceutical and biotechnology companies working on rare and neglected illnesses. The program provides expertise and resources, working with research partners to move therapeutics through preclinical testing, including plans for clinical trials and submission of an IND application to the Food and Drug Administration. These efforts effectively “de-risk” therapeutic candidates and make them more attractive for adoption by outside business partners. To learn more about the TRND program goals, please visit <https://ncats.nih.gov/tmd/about/goals>

### **Bridging Interventional Development Gaps (BrIDGs)**

The Bridging Interventional Development Gaps (BrIDGs) program enables research collaborations to advance candidate therapeutics for both common and rare diseases into clinical testing. Investigators do not receive grant funds through this program. Instead, selected researchers partner with NCATS experts to generate preclinical data and clinical-grade material through government contracts for use in Investigational New Drug (IND) applications to a regulatory authority such as the Food and Drug Administration (FDA). In general, BrIDGs provides synthesis, formulation, pharmacokinetic and toxicology expertise and resources to its collaborators.

NIH contractors conduct preclinical studies under the direction of NCATS staff. NCATS, along with any co-funding NIH Institutes and Centers, supports contract costs. The decision to collaborate on a proposed project is based on an internal assessment of scientific merit, programmatic fit and the availability of NIH funds. To find out how to submit a proposal to BrIDGs, please visit <https://ncats.nih.gov/bridgs/work>

As of fall 2015, BrIDGs has generated data to support 18 investigator-initiated INDs that have been cleared by the FDA and one clinical trial application cleared by Health Canada. A total of 14 projects have been evaluated in clinical trials. Five BrIDGs-supported agents have been evaluated in Phase II human clinical trials, in which researchers give an experimental therapy to a group of patients to evaluate the effectiveness and safety of a treatment. Third-party organizations have licensed or invested in 10 agents during or after their development by BrIDGs. To learn more about active and completed BrIDGs projects, please visit <https://ncats.nih.gov/bridgs/projects>

### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

Occasionally, NCATS may accept Phase IIB SBIR Competing Renewal grant applications of NCATS supported Phase II awards to continue research and development of products that have a potential to address bottlenecks in the translational process, and where additional time and effort is needed to reach a stage where interest and investment by third parties would be likely. Such products are expected to have broad applicability and be consistent with the mission of NCATS. Applicants are strongly encouraged to speak to NCATS Program staff prior to submitting their Phase IIB application. Budgets for Phase IIB grant applications must be approved by NCATS Program staff prior to submission.

## **Clinical Trials**

Does NCATS accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No	
Does NCATS accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does NCATS support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	U01 – however the SBC can <u>only</u> participate if repurposing an existing drug or biologic (therapeutics) that have already completed at least a Phase I trial for a different indication by the time an award is made. These pharma drugs and biologics are listed in PAR-18-332. <a href="https://grants.nih.gov/grants/guide/pa-files/PAR-18-332.html">https://grants.nih.gov/grants/guide/pa-files/PAR-18-332.html</a>

## **Research Topics**

### **Preclinical Drug Discovery and Development**

- Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact; such as those that are: implicated for disease, have genetic variations that have been identified in functional regions of receptor targets, and/or have high potential for biased signaling that would promote the beneficial effects of receptor signaling and reduce the unwanted effects
- Tools and technologies to enable high throughput screening of compound activity on currently “non- druggable” targets
- Assays for high-throughput screening of rare-diseases-related targets
- Co-crystallization high-throughput screening techniques
- Fluorescence probes to replace antibodies for determination of cellular protein translocation
- Phenotypic assay development, including stem cell technology platforms for human “disease-in-a- dish” applications and the evaluation of toxicity
- Interventions that target molecular pathways or mechanisms common to multiple diseases
- Platforms for non-antibody biologics, cell-based therapies and gene therapy discovery
- Small molecule and biologics analytical characterization
- Accelerated bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics and/or diagnostics
- Development of novel technologies for enzyme replacement therapies (e.g., new cell culture/expression system) to solve major bottlenecks in rare diseases research
- Innovative methods to determine alternative uses for existing therapeutic interventions for high priority areas, such as rare diseases and pain.
- Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic or other intervention optimization
- Technologies to deliver nucleic acid therapeutics to tissues other than the liver
- Methodologies and technologies to increase efficiencies of manufacturing therapeutics
- Development of novel high-throughput technologies that focus on making translational research more efficient
- GMP production of exosome/extracellular vesicles
- Generation of producer lines for large scale production of exosomes/extracellular vesicles
- Extracellular RNA-based biomarkers and therapeutics of human diseases
- Approaches to targeting the human microbiome for therapeutic or diagnostic purposes

- Scale up, manufacturing and characterization of IPS cells
- 3D printing technologies
- Technologies to substantially improve the efficiency and reduce the cost of clinical grade gene therapy vector manufacturing
- Development of in vitro human tissue models (organs, 3D printing)
- Technologies to allow therapeutic proteins other than lysosomal enzymes to be secreted and taken up by other cells via cross-correction
- Novel strategies to prevent deleterious immune responses to gene therapy, to improve efficiency genome editing and/or enzyme replacement therapy
- Establishing more robust phenotypic screens that may help prioritize candidate compounds for further testing
- Innovative technology for non-small molecule delivery
- High-throughput epigenetics screening/characterization tools and technologies
- Microphysiological systems (MPS)/Tissue Chips, including MPS/Tissue Chips that incorporate known functional variants, e.g., ACMG 59 or CPIC A alleles, for study comparison using the same derived genetic background across a set of tissue chips with the functional variant
- Volatile organic compounds (odors, scents) as biomarkers for disease
- Bacteriophage-based therapeutics for disease and as modulators of the microbiome and microbiome natural products
- High throughput Surface Plasmon Resonance devices for detecting protein small molecule interactions
- New class of quantum-enabled sensing technologies for advancing translational sciences (e.g., point of care ultrasensitive high-throughput technologies for diagnostics, and miniaturized benchtop technologies for chemical/bioanalyte characterization).
- Development of diagnostics or useful drug targets for rare diseases by using Pangenome data.

### **Biomedical, Clinical, & Health Research Informatics**

- Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays, and/or technologies with evidence about their use in research studies
- Cloud-based tools and methods for meaningful sharing, re-use and integration of research data
- Novel platforms, technologies and tools for: (1) enabling clinical and translational research, particularly those with mechanisms for inclusion of patient-reported data and (2) integration of patient data collected from multiple devices and multiple/diverse clinical studies
- Development of personalized phenotypic profiling (as well as personalized intervention) based on patient-centered integration of data from multiple data sources, including social media
- Development of predictive models for translational science
- Digital applications and tools (including telemedicine platforms) that facilitate/enhance translational research and medicine in rural populations
- Generic Disease Registry template platforms that can be reused for multiple diseases.
- Mobile device validation tools to ensure data from different brands or versions have compatible results.
- Tools to assess with algorithms developed with artificial intelligence, machine learning.
- Tools that allow for persistent identifier and attribution for data contributors that give credit to the data producers while ensuring that shared data has not been altered
- Patient Mobile Tool Platforms that facilitate tool developers to build “apps” that integrate



into their medical records.

- Tools and environments that enable an easy interrogation of publicly available data
- Innovative approaches like nanoneedles and nano particles to help improve early disease detection and targeted therapeutic delivery
- Tools and technologies that leverage AI and real-world data for enhanced product evaluation and surveillance that could be used to provide a resource for rapid response to public health needs

### **Clinical, Dissemination and Implementation Research**

- Tools and technologies that:
  - increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation and/or regulatory processes
  - evaluate and improve the process of informed consent
  - address medication adherence in clinical settings
  - address and improve community engagement
  - address the rapid diagnosis and/or clinical management of rare diseases
  - help characterize human disease states and assist in assessing the impact of interventions
  - support unique approaches to advance diversity, equity and inclusion.
  - mine published data and generate usable knowledge and analytics to advance research
- Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking
- Educational tools for clinical and translational science
- Computational or web-based health research methods, including:
  - Platforms for generally applicable and scalable multi-disease registries and natural history studies
  - Clinical trial designs and analyses (e.g., for pragmatic clinical trials)
- Approaches, tools, platforms and environments that:
  - Integrate data in novel ways for development of new biomarkers that can be tested in translational research paradigms for which there are barriers or bottlenecks
  - Engage prospective research participants who are from under-represented communities and impacted by disparities and the digital divide
- Strategies to enhance the quality of and accelerate the conduct of dissemination and implementation research
- Sustainable solutions for effective tools and environments in translational research
- Development and validation of patient reported outcomes, clinician-reported outcomes and biomarkers for rare diseases that are not already supported by a disease-specific NIH Institute or Center
- Patient empowerment tools/apps that allow users to compare their treatment and outcomes to normative populations existing treatment guidelines
- Telemedicine or digital health applications that focus on research in rural populations
- Tools and technologies that enhance the quality, safety, efficiency, effectiveness of new innovations in community settings

### **Contact Information**

For additional information on research topics, please contact:

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# NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

## **Mission**

The mission of NCCIH, as described in the Center's [Strategic Plan](#), is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care.

The following narrative indicates the scope of projects suitable for the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) programs that fit within the mission of NCCIH. For additional information about areas of interest to NCCIH and a listing of NCCIH's currently funded applications, please visit <https://www.nccih.nih.gov/research>. Business concerns interested in exploring SBIR/STTR grant opportunities with NCCIH are encouraged to visit the [NCCIH SBIR website](#) and contact NCCIH program directors prior to submitting an application.

## **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the Small Business Association (SBA), which can be found on the [NIH SEED website](#). NCCIH policy on grant duration is described in [NOT-AT-20-017](#).

There is an [SBA-Approved Waiver Topics](#) list, for which NCCIH generally will not fund:

- Phase I applications greater than \$325,000 total costs per year or project periods greater than 2 years.
- Phase II applications greater than \$2,000,000 total costs for the duration of the project or project periods greater than 3 years.

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

## **Specific SBIR and STTR Program Information**

NCCIH supports the development and validation of innovative technology to advance fundamental understanding, enhance and monitor usage, or determine the usefulness and safety of a variety of complementary and integrative health approaches, including natural products and/or mind and body approaches.

## **Specific Funding Opportunities and Programs**

NCCIH does not accept applications for Phase IIB.

[NOSI-AT-21-001](#) Development and/or Validation of Devices or Electronic Systems to Monitor or Enhance Mind and Body Interventions (SBIR/STTR)

[NOSI-AT-20-015](#) Methods Development in Natural Products Research (SBIR/STTR)

**Clinical Trials**

<p>Does NCCIH accept clinical trials through the Omnibus/Parent Notices of Funding Opportunities?</p>	<p>Yes</p>	<p>For applications involving clinical studies that fall within the NIH definition of a clinical trial, <b>NCCIH will not support clinical trials</b> aiming to test efficacy/effectiveness (meaning the study is powered on a primary outcome that is a clinical assessment used in clinical diagnosis of disease or monitoring of disease severity) of an intervention <b>as a part of an SBIR/STTR Phase I application</b>. Applicants seeking to conduct efficacy or effectiveness clinical trials should pursue funding via other Notices of Funding Opportunities (NOFOs) such as the Omnibus SBIR/STTR Phase II and Fast-Track.</p> <p>NCCIH recognizes a difference between “clinical trials” that are designed to answer specific questions about the clinical effect of interventions and mechanistic studies that have the primary goal of understanding how an intervention works.</p> <p>A clinical outcome study has the objective of determining the clinical safety, tolerability, feasibility, efficacy, and/or effectiveness of pharmacologic, nonpharmacologic, behavioral, biologic, surgical, or device (invasive or noninvasive) interventions.</p> <p>A mechanistic study has the objective to understand the mechanism(s) of action of an intervention, a biological or behavioral process, or the pathophysiology of a disease/condition.</p> <p><b>NCCIH continues to accept clinical trials of all types on Omnibus SBIR/STTR Phase II and Fast-Track applications.</b></p> <p>See <a href="#">NOT-AT-19-012</a> for “NCCIH Policy for SBIR and STTR Phase I Applications Proposing Clinical Trials to the Omnibus Solicitations”</p>
<p>Does NCCIH accept clinical trials through specific Notices of Funding Opportunities?</p>	<p>Yes</p>	

Does NCCIH support clinical trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	<a href="#">Notice of Special Interest (NOSI): Fundamental Science Research on Complementary and Integrative Health Approaches, Including Natural Products or Mind and Body Interventions</a>  <a href="#">Mechanisms Underlying the Contribution of Sleep Disturbances to Pain (R01 Clinical Trial Optional)</a>  <a href="#">Mechanisms Underlying the Contribution of Sleep Disturbances to Pain (R21 Clinical Trial Optional)</a>  <a href="#">Center of Excellence for Research on Complementary and Integrative Health (P01 Clinical Trial Optional)</a>  <a href="#">Investigator Initiated Clinical Trials of Complementary and Integrative Interventions Delivered Remotely or via mHealth (R01 Clinical Trial Required)</a>  <a href="#">Notice of Special Interest: Exploring the Mechanisms Underlying Analgesic Properties of Minor Cannabinoids and Terpenes</a>
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### **Research Topics**

**Natural Products** (including botanicals, herbs, probiotics, prebiotics, dietary supplements, special medicinal diets, and microbiome- /microbial-based therapeutics):

- Development and validation of technologies for standardization and characterization of biologically active ingredients in natural products.
- Development and validation of technologies for taxonomic identification of botanical raw materials or detection of adulterants.
- Development and validation of technologies for the identification and characterization of bioactive metabolites derived from oral consumption of natural products.
- Development and validation of methods for the sustainable production of low-yield natural products of commercial interest.
- Development of novel analytical tools and technologies to study the microbiome, including its composition, genetics, and bioactivity, that can help clarify associations between the human microbiome and brain function and health.
- Development of gut microbiome monitoring assays for validating safety and functional analysis of genomic and microbiota interactions.
- Development of complementary and integrative therapeutic approaches to modify and balance the gut microbiota in healthy populations and individuals with disrupted microbiota and related diseases.
- Clinical testing of natural products for the management of hard-to-treat symptoms such as pain, sleep disorders, or mild-to-moderate anxiety and depression to allow development of an evidence base that would accelerate U.S. Food and Drug Administration (FDA) approval of a drug indication for the natural product.

**Mind and Body Approaches** (including meditation, mindfulness, hypnosis, yoga, tai chi, acupuncture, manual therapies, and music/art therapies):

- Development, testing, and validation of appropriate objective and/or quantitative measures and instruments to assess or monitor mind and body approaches in different contexts (e.g., classrooms, families, child welfare, juvenile justice systems).
- Development, testing, and validation of measures and tools to assess training or fidelity of implementation of mind and body approaches in different settings (e.g., health care, community, families, schools, child welfare, juvenile justice systems).
- Development and testing of technologies for the implementation of mind and body approaches in group or individual settings and/or self-care strategies. Examples may include but are not limited to the use of mobile health technologies such as smartphone apps, sensors, online delivery, or phone-based delivery.
- Development and validation of methods for standardization and characterization of the active components of mind and body approaches.
- Development and validation of methods for standardization of multimodal interventions to study whole person health.
- Development and validation of imaging tools or instruments for studying manual therapies, including but not limited to massage, acupuncture, or spinal manipulation.
- Development and testing of innovative technologies for multisensory delivery of mind and body approaches.
- Development, testing, and validation of innovative technologies to enhance sensory-based (temperature, light, olfaction, etc.) therapies.
- Development, testing, and validation of innovative technologies to facilitate delivery of music/art-based interventions and to identify novel outcome measures and biomarkers for these interventions.

#### **General Tool/Technology Development:**

- Development and validation of biomarkers that correlate with efficacy of complementary and integrative health approaches.
- Development and validation of standardized, reliable, and cost-effective tools that correlate with brain imaging in response to mind and body interventions.
- Development and validation of tools, technologies, and instruments, including gaming and virtual reality technologies, for the accurate assessment of adherence and/or fidelity to the use of mind and body practices and interventions.
- Development and validation of tools to improve patient-reported outcome measures of importance in clinical studies of complementary and integrative health approaches.
- Development, pilot testing, and validation of wireless technologies for real-time data collection and monitoring of brain activity or other physiological signals for mind and body approaches.
- Development or adaptation of biochemical or epigenetic monitoring devices for complementary and integrative health approaches.
- Development and validation of tools to improve biological and physiological outcome measures for use in clinical studies of complementary or integrative health approaches.
- Development or adaptation of technologies for objective assessment of pain with relevance to complementary and integrative health approaches.
- Development of sleep monitoring technologies or biomarker panels to assess sleep deprivation, sleep deficiency, circadian rhythm dysregulation, and connection of sleep disturbances with health risks.
- Development and testing of *in vivo* labeling technology of tissues or cells responsible for generating signals in response to different internal senses (e.g., mechanical force, temperature, osmolarity, oxygen levels).
- Development and testing of technology or methods for quantifying biomechanical forces applied to internal tissues or cells.
- Development and testing of mobile health technology or nonmobile technology and methods to monitor or quantify physical and/or emotional well-being, breathing, or sleep.

### **Contact Information**

For additional information on research topics, please contact:

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## NATIONAL LIBRARY OF MEDICINE (NLM)

### Mission

The National Library of Medicine (NLM) offers support for research and development projects in biomedical informatics and data science. Biomedical informatics and data science research applies computer and information sciences to improve the access, storage, retrieval, management, dissemination and use of biomedical information. Grants are made to U.S. small businesses that seek to undertake informatics research and development leading to commercialization. Critical research areas include: representation of medical knowledge in computers; organization and retrieval issues for image databases; enhancement of human intellectual capacities through virtual reality, dynamic modeling, artificial intelligence, and machine learning; medical decision-making; linguistic analyses of medical languages and nomenclatures; investigations of topics relevant to health information or library science; biotechnology informatics issues; and informatics for disaster management. For additional information about areas of interest to NLM and a listing of NLM funded applications, please visit <http://www.nlm.nih.gov/ep>. Business concerns interested in exploring SBIR/STTR grant opportunities with NLM are encouraged to contact the NLM representatives prior to submitting an application.

### Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). For budgetary, administrative, or programmatic reasons, the NLM may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to the NLM that can be found in the [SBA-Approved Waiver Topics](#). **Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.**

### Specific SBIR and STTR Program Information

#### **NLM Clinical Trials Topics**

NLM will not accept SBIR applications that propose clinical trials, and all of the topics listed must be for projects that do not propose clinical trials.

#### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

NLM does not accept Phase IIB applications and does not participate in the CRP program.

### Clinical Trials

Does NLM accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does NLM accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	
Does NLM support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	Yes	



## **NLM Research Topics**

NLM's SBIR/STTR grant programs are focused on areas of particular interest from small business. The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NLM. They are not listed in priority order.

1. Development of new, innovative tools and methods for annotating, curating, and managing biomedical data resources
2. Advanced information retrieval and knowledge discovery from very large and/or heterogeneous data sets to support biomedical research
3. Development of novel approaches enabling analysis and discovery at scale across biomedical domains, research institutions, or health care sectors, including those leveraging high-performance cloud computing and federated learning
4. Novel platforms, technologies, tools, and techniques enabling multimodal data analysis to support health research or health care applications
5. Multi-level, reusable, data analytic models, simulations, information visualization, and presentation approaches to enhance decisions, learning or understanding of biological and clinical processes
6. Computational approaches integrating structured and unstructured data, natural language processing, automated metadata assignment to support biomedical research
7. Data science methods, approaches, or tools that enhance the quality, confidentiality, security, and/or utility of biomedical data, including personal health information
8. Artificial Intelligence techniques for characterizing and minimizing the impact of errors, incompleteness, missingness, within health-related data sets
9. Novel data-driven methods to facilitate real-time decision-making in clinical practice and public health
10. Analytical tools, technologies, and other data-driven strategies to track disease outbreaks, epidemics, and pandemics
11. Tools and technologies for understanding and predicting climate and environmental effects on human health

## **Contact Information**

For additional information on research topics, contact:

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## **DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)**

### **Mission**

ORIP supports high-quality, disease-free animal models and specialized animal research facilities to help meet the needs of biomedical researchers to understand, detect, treat, and prevent a wide range of human diseases. This support enables discoveries at molecular, cellular, and organ levels that lead to animal-based studies which then are translated to patient-oriented clinical research, aiming to find treatments to ameliorate or cure common and rare diseases. Through the small business Phase I, Phase II, Fast-track, Direct Phase II and Phase IIB awards, ORIP is especially interested in funding research to develop preclinical methods and technologies to reduce or replace animal use with novel alternative methods, improve animal models of human diseases, and the care, use, and management of laboratory animals. ORIP also encourages the development and implementation of technologies to directly benefit the welfare of research animals and to directly improve animal facilities that support biomedical and behavioral research.

A list of some potential ORIP program topics follows the description of our Phase IIB Competing Renewal Awards. For additional information about ORIP, please visit our home page at <https://orip.nih.gov/>.

### **Budget Guidance**

Total funding support (direct costs, indirect costs, fees) normally may not exceed the amounts defined by the SBA, which can be found on the [NIH SEED website](#). For budgetary, administrative, or programmatic reasons, ORIP may not fund an application, may decrease the length of an award, and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by the SBA for specific topics relevant to ORIP that can be found in the [SBA-Approved Waiver Topics](#). **Applicants who have budget questions or are considering requesting a budget greater than these amounts are strongly encouraged to contact program staff before submitting an application.**

### **Specific SBIR and STTR Program Information**

#### **ORIP Clinical Trials Topics**

ORIP will not accept SBIR applications that propose clinical trials. All the topics listed below are for projects that do not propose clinical trials.

#### **Specific Funding Opportunities and Programs**

In addition to the Omnibus program announcement, ORIP has targeted Notices of Funding Opportunities (NOFOs). Please visit our [ORIP Funding Opportunities webpage](#) to view the latest targeted NOFOs.

#### **Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)**

ORIP will only accept Phase IIB SBIR Competing Renewal grant applications of ORIP-supported Phase II awards to continue research and development of methods, technologies, tools, and devices for basic or translational research where extraordinary time and effort are needed for completion of these projects. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to

reach a stage where interest and investment by third parties would be more likely. Such products are expected to have broad applicability, consistent with the mission of ORIP. Budgets that do not exceed \$1 M per year in total costs (for up to 2 years), may be requested for this Phase IIB Competing Renewal opportunity; however, it is expected that, in most cases, the requested budget would not exceed the final year budget of the applicant's previous Phase II award. This opportunity is available for the SBIR program only.

Please contact your Program Officer before beginning the process of preparing a Phase IIB Competing Renewal application. In addition, prospective applicants are strongly encouraged to submit to the Program Contact (listed after each section) a letter of intent by email that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other Key Personnel
- Participating organizations
- Notice of Funding Opportunity Number (e.g., PA-22-XXX)

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. It is expected that only a few of ORIP SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

ORIP does not participate in the Commercialization Readiness Pilot (CRP) program at this time.

**Clinical Trials**

Does ORIP accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No
Does ORIP accept Clinical Trials through specific Notices of Funding Opportunities?	No
Does ORIP support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	No

**Research Topics**

**ORIP Non-Clinical Trials Topics:**

**Division of Comparative Medicine**

- A. Development of *in vitro* animal cell culture techniques, microphysiological systems (organs- on-a-chips, organoids) or computational (*in silico*) methods to reduce the number of animals used in studies and to replace certain tests conducted in animal models with novel alternative methods (NAMS).
- B. Development of improved reagents and cost-effective methods and technologies to accurately screen and diagnose selected diseases of laboratory animal, and to perform overall assessments of animal quality and health status. An urgent need currently exists for the development of improved methods for detection of active tuberculosis in nonhuman primates (NHPs).
- C. Development of improved reagents, techniques, and devices/tools for genomic and transcriptomic analysis and data mining from tissue or single cells of laboratory

animals and animal models of human diseases.

- D. Development of new technologies for rapid or high throughput animal characterization and deep phenotyping (at tissue, organ, cellular or molecular levels).
- E. Development of noninvasive, wearable technologies to identify or assess biomarkers in well validated animal models.
- F. Development of prophylactics or new therapeutic agents to prevent and/or control infectious diseases of laboratory animals. One high priority need is to develop methods to control and prevent monkey B virus (*Macacine alphaherpesvirus-1*) infections.
- G. Identification, development, and characterization of spontaneous (naturally occurring) and engineered vertebrate animal models for studies of various human diseases (excluding most random mutagenesis projects performed on rodents).
- H. Development and refinement of high-throughput technologies, cryoprotectants and devices for the cryopreservation, vitrification, long-term maintenance, and revival of cells, tissues and organs, as well as laboratory animal embryos and gametes, especially for *Drosophila*, aquatic models of biomedical value, swine, and NHPs.
- I. Development of technologies, tools, and devices for the effective monitoring of frozen, cryopreserved cells and biological materials/tissues as well as laboratory animal embryos and gametes (including monitoring conditions during their distribution).
- J. Development of technologies for improved embryo transfer within a single animal species or of intraspecific embryo transfer to allow preservation of rare or unique animal species that may have unique value in biomedical research as animal models for human disease.
- K. Development of improved reagents, artificial intelligence/machine learning technologies, tools, devices, and high-throughput technologies to perform, analyze, capture, and process data gathered in “omics” studies (genomics, transcriptomics, epigenomics, proteomics, lipidomics, glycomics, metabolomics, and phenomics, among others) in normal, diseased, and intervention conditions in animal/biological models to support or validate pre-clinical analyses.
- L. Development of biological tools and reagents for reconstruction, remodeling, repair, and regeneration of tissues damaged by injury or disease. Development of the technologies and procedures to test efficacy and safety of these experiments in animal models. Approaches to detect and track survival of implanted cells and tissues *in vivo*.
- M. Development of reagents (including antibodies), assays, and technologies that will facilitate research using aquatic biomedical models, such as zebrafish or *Xenopus*, for understanding basic aspects of development, physiology, or genetics.
- N. Development of reagents (including antibodies), assays, and technologies that will facilitate research using NHPs for understanding basic aspects of development, physiology, or genetics. High priority needs include reagents for NHP species other than the rhesus macaque.
- O. Development of rapid and sensitive technology for the accurate detection and diagnosis of polymicrobial infections in biomedical laboratory animal models, including those agents involved in vertical transmission of diseases into embryos and larvae.
- P. Technologies for improved sex determination of embryonic, neonatal, and juvenile stages of animals, with one high priority need being nonmammalian species.

- Q. Development of rapid and sensitive technology for the detection and study of emerging human pathogens in animal models.
- R. Development of non-invasive, micro-sensor technologies (e.g., embedded sensors, devices, microchips) for NHPs and other live animal models to collect data related to neuroimaging, behavioral and cognitive assessments, metabolism, microbiomes, and other biomedical research areas. Of special interest are wearable, swallowable sensitive and selective probes/sensors for detecting physiological fluctuations in living animals, with the capability of monitoring at deep tissues level.
- S. Development of technologies for cell-based therapies that could be used as implantable biocomputers in animal models of human disease, to perform complex logic computations that integrated signals from multiple metabolites/pathways. These include remote-controlled switches and natural, nontoxic, highly soluble, and potentially beneficial to health trigger molecules.
- T. Development of technologies and tools (biosensors, imaging approaches, and reagents such as antibodies (especially nanobodies)), to facilitate validation and use of multiple model organisms in research studies to enhance the rigor, and reproducibility of animal research and their clinical and translational research potential.

### **Division of Construction and Instruments**

The Division of Construction and Instruments supports the development and implementation of technologies that enhance and improve the welfare and research facilities of animal models in biomedical and behavioral research. In particular, the areas being supported include novel tools and equipment that improves and facilitates the care and monitoring of animals. One area of interest is the integration of technological features for detecting, measuring, monitoring, recording, analyzing, and reporting physiological, biobehavioral, and environmental conditions to allow for documenting these physiological parameters and extrinsic factors and enhancing scientific rigor and reproducibility in animal studies. Another area of interest encompasses the improvement of laboratory equipment to maintain the environmental conditions and upkeep of the infrastructure within animal facilities. Of special importance is the employment of green technologies. Examples of topics of special interest include (but are not limited to) the development of better, more reliable, and more efficient:

- A. Equipment such as vacuum cleaners, air filters, hoods, snorkels, and autoclaves for animal research facilities, for barrier facilities, and other facilities with special needs and requirements.
- B. Equipment/devices to distribute water and food and to monitor and record their intake by research animals.
- C. Equipment to increase the quality of life and prevent injuries of research animals, staff, and investigators.
- D. Technology to monitor and protect the well-being of animals, including IT-supported tools.
- E. Equipment and its use for maintenance of disease-free colonies and healthy animals.
- F. Equipment to disinfect devices, furnishings, and other apparatus in animal facilities such as aquaria, cages, tunnels, and racks.
- G. Cost-effective husbandry and colony management techniques, equipment, and/or new approaches to improve laboratory animal welfare and assure efficient and appropriate research use.
- H. Specialized equipment and caging for laboratory animals to permit optimal

environmental control, and operational efficiency, including improvements in caging, identification/tagging of animals and remote monitoring in animal facilities.

- I. Specialized equipment to permit integrated environmental factor measuring, monitoring, reporting, recording and documentation (such as for air quality, temperature, humidity, lighting, sound, and vibration level).

### **Contact Information**

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## **OFFICE OF RESEARCH ON WOMEN'S HEALTH**

### **Mission**

ORWH is the first Public Health Service office dedicated specifically to promoting women's health research within and beyond the NIH scientific community. ORWH was established in September 1990. [Congress assigned a far-reaching leadership role for ORWH](#) by mandating that the ORWH Director:

- Advise the NIH Director and staff on matters relating to research on women's health
- Strengthen and enhance research related to diseases, disorders, and conditions that affect women
- Ensure that research conducted and supported by NIH adequately addresses issues regarding women's health
- Ensure that women are appropriately represented in biomedical and bio-behavioral research studies supported by the NIH
- Develop opportunities and support for recruitment, retention, reentry, and advancement of women in biomedical careers
- Support and advance rigorous research that is relevant to the health of women
- Ensure NIH-funded research accounts for sex as a biological variable (SABV)

ORWH crafts and implements the [NIH-Wide Strategic Plan for Women's Health Research](#) in partnership with NIH Institutes and Centers (ICs) and co-funds research on the role of sex and gender on health. ORWH also collaborates with NIH ICs, the NIH Office of Extramural Research, and the NIH Office of Intramural Research to monitor adherence to NIH's inclusion policies, which ensure that women and minorities are represented in NIH-supported clinical research.

### **Budget Guidance**

ORWH does not award grants but co-funds women's health-related applications that have received an award from one of the participating NIH Institutes and Centers (ICs) listed in the announcement. Budgets should be discussed with Institute or Center program staff, not ORWH.

### **Specific SBIR and STTR Program Information**

The NIH Office of Research on Women's Health is technology agnostic and welcomes applications focused on diseases and health conditions that predominantly affect women (e.g., autoimmune diseases; depressive disorders, Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), gender-based-violence), present and progress differently in women (e.g., cardiovascular disease; HIV; reproductive aging and its implications), or are female-specific (e.g., uterine fibroids; endometriosis; menopause).

### **Specific Funding Opportunities and Programs**

In addition to the Omnibus program announcement, for a current list of funding announcements and programmatic initiatives visit: <https://orwh.od.nih.gov/research/funded-research-and-programs/funding-opportunities-and-notice>

### **Research Topics**

ORWH will consider co-funding for applications that have a central focus on the health of women, as demonstrated through specific aims that ***EITHER*** explicitly address a particular condition in women ***OR*** focus on one of the high priority topics below. In either approach, intersectional and/or multidimensional approaches that consider the health of women in context (e.g., projects accounting for social and structural variables— including race, ethnicity, socioeconomic status, and State and Federal policies— that affect women’s health) are strongly encouraged. While projects are not required to exclusively focus on women for ORWH co-funding, studies that include more than one sex or gender should be designed and powered to make generalizable conclusions about women and enable sex or gender difference comparison.

ORWH intends to prioritize interdisciplinary research that:

- Addresses the influence of sex-linked biology, gender-related factors, or their intersections on health.
- Addresses how physical, mental, and psychological health outcomes interact with structural factors to either mitigate or exacerbate health disparities and aims to create behavioral interventions to address these issues.
- Advances the translation of research advancements and evidence in women’s health into practical benefits for patients and providers.
- Informs and develops multi-sector partnerships to advance innovation in women’s health research.
- Increases public awareness of the need for greater investment in and attention to women’s health research, as well as women’s health outcomes across the lifespan.
- Advances research to reduce health disparities and inequities affecting women’s health, including those related to race, ethnicity, age, socioeconomic status, disability, and exposure to environmental factors and contaminants that can directly affect health.
- Increases uptake of evidence-based interventions that advance women’s health.
- Addresses topics identified in the [Women’s Health Innovation Opportunity Map](#).
- Reduces violence, stigma, and trauma related to HIV.
- Develops woman-centered self-tests for HIV viral load monitoring, including in breast milk.
- Develops topical microbicide agents, wearable, implantable, or insertable devices releasing medications alone or as part of multipurpose prevention technologies (MPTs), to prevent sexual acquisition of HIV, other sexually transmitted infections and/or unplanned pregnancy across the lifespan including in pregnant or postpartum people.
- Promotes the use of advanced statistical modeling, data visualization, artificial intelligence (AI), and machine learning (ML) methods for research on the health of women.
- Develops methods, tools, or technologies to increase data sharing and improve data management practices to align with the Findability, Accessibility, Interoperability, and Reusability (FAIR) data principles and enhances the utility of new and existing data on the health of women.
- Methods for integrating data science, including artificial intelligence and machine learning, into research on the health of women.
- Develops cutting-edge computational tools and technologies to facilitate screening for prevention, diagnosis, and treatment of diseases that affect women.
- Improves estimates of the impact of chronic conditions in women, including projects to diagnose and reduce misclassification of female-specific and gynecologic conditions, conditions that predominantly impact women or affect women differently, and projects to characterize differences in chronic condition presentation by gender, race and ethnicity,



and the various structural and social determinants that these women experience or are affected by.

- Explores the role of hormonal fluctuations on the development of chronic conditions in women, including the influence of age of menarche; the role of menstrual cycle irregularity/regularity, length, and phase; the length of the reproductive window; the link between adverse pregnancy outcomes and development of chronic conditions later in life; and the effect of exogenous hormones on the development of chronic conditions
- Develops new and better approaches for addressing the symptoms that affect women during perimenopause, menopause, and postmenopause
- Improves early and accurate detection and diagnosis of chronic conditions in women, including the diagnosis of multiple chronic conditions
- Elucidates gender differences in access and use of health care services, including methods for assessing discrimination (e.g., sexism, racism, ageism, and homophobia) encountered by women when accessing health care services for chronic conditions.

### **Contact Information**

For additional information on ORWH priorities, please contact:

Elizabeth Barr, Ph.D.

ORWH Associate Director for Interdisciplinary Research

Office of Research on Women's Health, NIH

Phone: 301-402-7895

Email: [Elizabeth.Barr@nih.gov](mailto:Elizabeth.Barr@nih.gov)

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## CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. For more than 70 years, we've put science into action to help children stay healthy so they can grow and learn; to help families, businesses, and communities fight disease and stay strong; and to protect the public's health.

### Vision

Equitably protecting health, safety, and security.

### Mission

CDC works [24/7](#) to protect America from health, safety, and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable, or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats and responds when these arise.

The [2022-2027 CDC Strategic Plan](#) advances science and health equity and affirms the agency's commitment to one unified vision — equitably protecting health, safety, and security. The plan leverages five core capabilities of the agency to include: a diverse public health workforce, world-class data and analytics, state-of-the-art laboratories, rapid response to outbreaks at their source, and strong global capacity and domestic preparedness. Our work is underscored by the agency's [Pledge to the American People](#) and dedication to use timely data and science to drive and communicate customer-centered, high-impact public health action.

### Budget Guidance

Total funding support (direct costs, indirect costs, fees) normally may not exceed \$306,872 for Phase I awards and \$2,045,816 for Phase II awards. These are the amounts currently defined by the U.S. Small Business Administration (SBA), which can also be found on the [CDC SBIR website](#). Applicants considering a requested budget greater than these limits are **strongly encouraged** to contact CDC program staff before applying. For budgetary, administrative, or programmatic reasons, the CDC may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. CDC has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations set by SBA for specific topics relevant to CDC that can be found in the [SBA-Approved Waiver Topics Over Statutory Budget Limitations document](#).

Before considering and/or preparing an application to the CDC SBIR program, applicants are encouraged to review the websites of CDC's participating components and to contact the SBIR program staff listed below.

### Specific SBIR and STTR Program Information

CDC does not accept STTR applications.

CDC does not accept Direct to Phase IIs, Fast-Track, or Phase IIB.

For additional information about CDC, please visit: <http://www.cdc.gov>.

### **Specific Funding Opportunities and Programs**

#### **Clinical Trials**

Does CDC accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	Yes	
Does CDC accept Clinical Trials through specific Notices of Funding Opportunities?	Yes	

#### **Research Topics/Specific Areas of Interest**

Additional information on the awarding components (CIOs) and their research interests is available electronically on the home pages shown throughout the “Research Topics/Specific Areas of Interest” sections below.

CDC encourages investigator-initiated applications that focus on support for the prevention, detection, and response to emerging public health threats. CDC also encourages investigator-initiated applications that align with the agency’s overall mission and the research areas of interest of the participating CDC components below.

#### **Contact Information**

General questions about the CDC SBIR program should be directed to:  
Small Business Innovation Research Program (SBIR)  
Office of Science (OS)  
Centers for Disease Control and Prevention (CDC)  
Email: [SBIR@cdc.gov](mailto:SBIR@cdc.gov)

#### **GLOBAL HEALTH CENTER (GHC)**

#### **Mission and Research Areas of Interest**

CDC’s global health mission is to improve and protect the health, safety, and security of Americans while reducing morbidity and mortality worldwide. CDC’s Global Health Center works to protect Americans from dangerous and costly public health threats, including COVID-19, vaccine-preventable diseases, HIV, TB, and malaria—responding when and where health threats arise.

Goals of the center include:

- Protecting Americans and populations across the globe by strengthening global public health prevention, detection, and response (Health Security)
- Saving lives, improving health outcomes, and fostering healthy populations globally (Health Impact)
- Leading and influencing the advancement of global public health science and practice and serving as a leading source of credible scientific information (Public Health Science Leadership)

GHC seeks to accomplish its goals by:

- Leveraging the latest technologies and advanced analytics to accelerate public health impact
- Eliminating health disparities and achieve optimal health for all
- Establishing and strengthening sustainable country, regional, and international public health systems

- Fostering health diplomacy in coordination with other U.S. Government agencies through its longstanding bilateral and multilateral partnerships, engagement with the private sector, and ongoing collaborations with academic institutions and foundations
- Availing its workforce to address the most urgent global public health threats

Additionally, GHC encourages submission of research applications with innovative research technologies designed to reduce health disparities and promote health equity.

Please visit the GHC website at: <https://www.cdc.gov/GlobalHealth/>.

**Description of Research Areas of Interest**

Areas of focus include:

- Achieving an AIDS-Free generation
- Innovating TB and Malaria prevention and treatment
- Optimizing the impact of pneumococcal conjugate vaccine
- Eradicating polio and combating vaccine-preventable diseases
- Eliminating epidemic meningitis in Africa
- Improving country capacity to detect and respond to outbreaks and prevent future ones
- Training a multidisciplinary, global workforce
- Improving in-country emergency response capacity
- Maintaining a rapid response capacity at CDC to respond to international public health emergencies
- Analyzing data to best inform programming in limited resource settings
- Rapidly translating data to improve public health outcomes

**Examples of specific research areas of interest include, but are not limited to:**

- Advanced tools and techniques for detecting new microbes, biomarkers, and cases
- Non-traditional surveillance tools and methods for real-time detection of emerging public health threats, including COVID-19, vaccine-preventable diseases, HIV, TB, and malaria
- Virtual reality equipment and software to support the development of virtual laboratory environments to assess practical laboratory skill competency
- Technologies to detect diseases faster

**Impact and Commercialization Potential:**

This research could lead to the development of tools for the detection of diseases and improve the ability to rapidly respond to emerging public health threats. Successful and novel innovation that will lead to the development of these tools and technologies will have huge commercial potential across many markets.

For GHC programmatic information, contact:

Lata Kumar, MS, MPH, MBA  
 Office of the Director  
 Center for Global Health Center  
 Centers for Disease Control and Prevention (CDC) Mail Stop H21-9  
 1600 Clifton Road NE Atlanta, GA 30329  
 Phone: (404) 639-7618  
 Email: [LKumar@cdc.gov](mailto:LKumar@cdc.gov)

For grants specific, administrative information, contact:

Angie Willard, Team Lead  
Office of Grant Services  
Office of Financial Resources  
Office of the Chief Operating Officer  
Centers for Disease Control and Prevention (CDC)  
Mail Stop TV-2  
2939 Flowers Road NE  
Atlanta, GA 30341  
Phone: 770-498-2596  
Email: [AEN4@cdc.gov](mailto:AEN4@cdc.gov)

## **NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES (NCBDDD)**

### **Mission and Research Areas of Interest**

The mission of CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) is to promote the health of babies, children, and adults and to enhance the potential for full, productive living. To achieve its mission, the Center works to identify the causes of birth defects and developmental disabilities, helps children to develop and reach their full potential, and promotes health and well-being among people of all ages with disabilities, including blood disorders. NCBDDD seeks to accomplish these goals through research, partnerships, and prevention and education programs. Our efforts in surveillance, research, and health promotion programs provide information used to identify causes of birth defects and infant disorders, find opportunities to prevent them, and improve the health of those with these conditions. Additionally, NCBDDD encourages submission of research applications with innovative research technologies designed to reduce health disparities and promote health equity.

Please visit the NCBDDD website at: <http://www.cdc.gov/ncbddd/index.html>.

### **Description of Research Areas of Interest**

Goals of the center include:

- Improving the health and developmental outcome of children and adults with or at risk of disabilities
- Preventing complications and improving the management of blood disorders
- Addressing preventable causes of birth defects, infant disorders, and related conditions
- Promoting and improving the health of people living with birth defects, infant disorders, and related conditions

### **Examples of specific research areas of interest include, but are not limited to:**

- Improved methods for screening for newborn heart disorders
- Technology-based solutions to improve access to evidence-based interventions to manage attention-deficit/hyperactivity disorder and tic disorders
- Tools and technologies to improve the life of people living with birth-defects
- Technologies that improve access of individuals with intellectual disabilities to services and evidence-based management interventions

### **Impact and Commercialization Potential:**

This research could lead to the development of tools for the management of birth defects and developmental disabilities, improve access to effective interventions among people with disabilities,

and lead to the development of devices and methods for the detection and management of birth defects. Effective tools and technologies have the potential for uptake by the intended populations and their caregivers.

For NCBDDD programmatic information, contact:

Natalie Brown, MPH  
Office of the Director  
National Center for Chronic Disease Prevention and Health Promotion  
Centers for Disease Control and Prevention (CDC)  
Mail Stop S107-8  
4770 Buford Highway  
Atlanta, GA 30341  
Phone: 404-639-4601  
Email: [NBrown3@cdc.gov](mailto:NBrown3@cdc.gov)

For grants specific, administrative information, contact:

Brownie Anderson-Rana  
Office of Grant Services  
Office of Financial Resources  
Office of the Chief Operating Officer  
Centers for Disease Control and Prevention (CDC)  
Mail Stop K-75  
2920 Brandywine Rd.  
Atlanta, GA 30341  
Phone: 770-488-2771  
Email: [BAAndersonRana@cdc.gov](mailto:BAAndersonRana@cdc.gov)

## **NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)**

### **Mission and Research Areas of Interest**

CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) carries out a variety of activities that improve the nation's health by preventing a range of chronic diseases such as arthritis, cancer, diabetes, heart disease, obesity, and stroke, while promoting health and wellness in the areas of reproductive health, oral health, nutrition, and physical activity. The Center's activities include supporting states' implementation of public health programs; public health surveillance; translation research; and developing tools and resources for organizations at the national, tribal, state, and community levels. NCCDPHP has identified the following Social Determinants of Health (SDoH) as priorities: built environment, clinical-community linkages, social connectedness, tobacco control policy, and food and nutrition security. Additionally, the Center encourages submission of research applications with innovative technologies designed to reduce health disparities and promote health equity.

Please visit the NCCDPHP web site at: <http://www.cdc.gov/chronicdisease/index.htm>.

### **Description of Research Areas of Interest**

The center's areas of focus include:

- Development, implementation, and promotion of effective strategies for preventing and controlling cancer

- Prevention of diabetes and diabetes complications
- Improving cardiovascular health for all, reducing the burden, and eliminating disparities associated with heart disease and stroke
- Supporting healthy eating, active living, and obesity prevention
- Promoting optimal and equitable health in women and infants
- Supporting efforts to protect the public's health from the harmful effects of tobacco use
- Improving symptoms and quality of life for people with conditions such as Alzheimer's disease, arthritis, epilepsy, and lupus
- Improving oral health by promoting proven interventions
- Working through schools to implement effective school-based strategies that help youth become healthy, successful adults

**Examples of specific research areas of interest include, but are not limited to:**

- Tools to increase access to health care, decision support tools to improve prevention, measurement, and management of chronic diseases
- Applications to improve nutrition among children and adults
- Implementation tools to improve use of evidence-based interventions such as chronic disease self-management programs
- Design aids to increase physical activity through the built environment
- Tools to promote physical activity and physical activity education among children
- Methods to improve access to screening
- Applications to reduce smoking and support quitting
- Interventions to promote prevention and early detection of cancers

**Impact and Commercialization Potential:**

This research could lead to the development of solutions to increase uptake of prevention interventions and increase access to screening services, as well as lead to the development of tools to monitor and manage chronic diseases, address health disparities among specific sub-populations, increase linkage to clinical and other support services, and result in prevention and better management of chronic diseases. Practical, easy to use, and effective solutions will have potential for uptake by large segments of the target populations.

For NCCDPHP programmatic information, contact:

Natalie Brown, MPH  
 Office of the Director  
 National Center for Chronic Disease Prevention and Health  
 Promotion  
 Centers for Disease Control and Prevention  
 (CDC)  
 Mail Stop S107-8  
 4770 Buford Highway  
 Atlanta, GA 30341  
 Phone: 404-639-4601  
 Email: [NBrown3@cdc.gov](mailto:NBrown3@cdc.gov)

For grants specific, administrative information, contact:

Angie Willard, Team Lead  
 Office of Grant Services Office of Financial Resources  
 Office of the Chief Operating Officer  
 Centers for Disease Control and Prevention (CDC)  
 Mail Stop, T2939 Flowers Road NE Atlanta, GA 30341

Phone: 770-498-2596  
Email: [AEN4@cdc.gov](mailto:AEN4@cdc.gov)

## **NATIONAL CENTER FOR EMERGING AND ZOO NOTIC INFECTIONOUS DISEASES (NCEZID)**

### **Mission and Research Areas of Interest**

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) aims to prevent disease, disability, and death caused by a wide range of infectious diseases. NCEZID focuses on diseases that have been around for many years, emerging diseases (those that are new or just recently identified), and zoonotic diseases (those spread from animals to people). Work is guided in part by a holistic "One Health" strategy, which recognizes the vital interconnectedness of microbes and the environment. Through a comprehensive approach involving many scientific disciplines, better health for humans and animals and an improved environment can be attained. Research to address reducing health disparities and increasing health equity is strongly encouraged.

Please visit the NCEZID website at: <http://www.cdc.gov/ncezid>.

### **Description of Research Areas of Interest**

#### **(1) Develop a Rapid, Portable, Point-of-Care Antifungal Therapeutic Drug Monitoring Tool**

***Background:*** Every year, an estimated 150 million severe fungal infections occur worldwide, resulting in approximately 1.7 million deaths. Antifungals drugs for treating severe fungal infections are limited to just 3 classes, and antifungal resistant infections are a rising global public health threat, underscoring an urgent need to optimize antifungal use to prevent mortality and minimize resistance selection pressure. Antifungal therapeutic drug monitoring is a critical component of individualized, precision treatment for fungal infections and for antifungal stewardship. It can help optimize individual patients' antifungal treatment regimen by measuring antifungal drug concentrations in a patient's biologic fluids and applying well-described pharmacokinetic principles to adjust drug dosing. Infectious Diseases Society of America's Guidelines for treatment of fungal diseases like candidiasis, aspergillosis, histoplasmosis, coccidioidomycosis, and blastomycosis recommend therapeutic drug monitoring for certain antifungals, particularly for triazole antifungals (e.g., itraconazole, voriconazole, Posaconazole). Antifungal therapeutic drug monitoring can help improve outcomes through minimizing toxicity associated with supratherapeutic drug levels and prevent treatment failure from subtherapeutic levels. Also, *in vitro* studies have shown that suboptimal drug levels can lead to antifungal resistance, supporting therapeutic drug monitoring's potential role in preventing the emergence of antifungal-resistant organisms. Measurement of antifungal concentrations is usually performed by analytical assays, such as high-performance liquid chromatography or liquid chromatography-mass spectrometry which are usually only available in large academic centers; bioassays are available for certain azole antifungals (e.g., itraconazole), but are difficult to interpret and can be inaccurate.

Recent studies suggest that antifungal therapeutic drug monitoring is underutilized, leading to missed opportunities to address sub- and supratherapeutic drug levels and improve patient outcomes. An analysis of a hospital discharge data set showed that only 16% of therapeutic drug monitoring-eligible patients receiving itraconazole, Posaconazole, or voriconazole had drug level monitoring performed. Among 55 predominately academic medical centers, only 41% of patients receiving isavuconazole,



Posaconazole, or voriconazole for treatment or prophylaxis of invasive fungal infections had therapeutic drug monitoring performed.

A recent survey found that there are many challenges encountered in performing antifungal therapeutic drug monitoring; the most common being long turnaround times for send-out tests. Other barriers noted were difficulty coordinating testing logistics, difficulty interpreting results, and cost.

**Specific Research Area(s) of Interest:** The major research priorities areas for NCEZID are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of NCEZID will also be considered through this Omnibus solicitation. Research to address reducing health disparities and increasing health equity is strongly encouraged.

The goals for the proposed research are to address fungal infections being treated with antifungals requiring therapeutic drug monitoring. Prioritized antifungals would be itraconazole, voriconazole, and Posaconazole.

**Examples of specific research areas of interest include, but are not limited to:**

- Development of rapid and novel strategies for measuring in vivo antifungal level in patient for therapeutic efficacy.

**Impact:** This research will lead to the development of practical, timely and innovative solutions to address barriers to performing antifungal therapeutic drug monitoring (e.g., long turnaround times, difficulty in coordinating logistics) to improve patient outcomes when being treated with prioritized antifungals.

**Commercialization Potential:** Current antifungal therapeutic drug monitoring is limited to large academic centers. Successful and novel innovation will improve patient outcomes and prevent toxicity and potentially resistance while having a large market with an increasingly population susceptible to fungal infections. Rural and urban, community and academic hospitals will be able to procure the innovative tools.

## **(2) Finding the cause of Guillain-Barré syndrome**

**Background:** Guillain-Barré syndrome (GBS) is a rare disorder where the body's immune system attacks part of the peripheral nervous system, resulting in symptoms ranging from brief weakness to devastating paralysis. The global incident rate of GBS is about 1-2 cases per 100,000 people per year, and the CDC estimates that about 3,000 to 6,000 cases of GBS occur every year in the United States. The cause of GBS is not fully understood, but is most frequently associated with *Campylobacter jejuni* infections, with about 1 in 1,000 people with *Campylobacter* infection developing GBS in the United States. Other risk factors include respiratory illnesses, viral infections, and vaccination. Finding an accurate cause for GBS is challenging, since symptom onset can occur weeks after the initial infection. In outbreaks of GBS that have occurred globally, determining the cause of GBS for accurate diagnosis and surveillance has proved to be difficult, especially in regions with limited resources.

**Specific Research Area(s) of Interest:** The major research priorities areas for NCEZID are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of NCEZID will also be considered through this Omnibus solicitation. Research to address reducing health disparities and increasing health equity is strongly encouraged.

The goal of the proposed research is to develop innovative methods to determine the cause of GBS.

**Examples of specific research areas of interest include, but are not limited to:**

- Developing cost-effective diagnostic tests for *Campylobacter* species from GBS patient samples.
- Enhancing surveillance by leveraging novel technologies to sequence type associated with specific serotypes of *Campylobacter jejuni*.

- Determining the cause of illness during a GBS outbreak.

**Impact:** This research will lead to finding innovative ideas to diagnose and perform surveillance on illnesses with ambiguous causes that can be difficult to determine using traditional methods.

**Commercialization Potential:** The innovative solutions developed through this research will have significant commercial potential in improving public's health both domestically and globally.

### **(3) Developing Novel Diagnostic Testing for Typhoid Disease**

**Background:** Typhoid fever is a significant global health concern, particularly in regions with limited access to healthcare facilities and resources. Traditional diagnostic methods for typhoid, such as blood culture and serological tests, have limitations in terms of accuracy, cost, and turnaround time. Therefore, there is an urgent need to develop novel diagnostic testing approaches that are rapid, affordable, and highly sensitive and deployable in resource limited settings.

**Specific Research Area(s) of Interest:** The major research priorities areas for NCEZID are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of NCEZID will also be considered through this Omnibus solicitation. Research to address reducing health disparities and increasing health equity is strongly encouraged. The goal of this proposal is to develop innovative methods to identify the cause of illness for suspected Typhoid fever. The proposed test method should improve the accuracy of existing diagnostic methods and be deployable in resource limited settings.

**Examples of specific research areas of interest include, but are not limited to:**

- Identify appropriate markers specific and sensitive for *Salmonella enterica* serotype Typhi detection from suspected cases of typhoid fever. This may involve techniques to analyze specific bacterial genomes or bacterial antigens.
- Design and optimize an assay based on the identified biomarkers using cutting-edge technologies that are user-friendly, require minimal equipment, field deployable, and provide rapid results.

**Impact:** This research will lead to innovative diagnostic approaches to address a challenging infectious disease that causes illness both domestically and internationally.

**Commercialization Potential:** Successful approaches will lead to faster and more accurate diagnoses and reduced disease, disability, and death and will have huge commercial potential across many markets.

### **(4) Develop new or enhanced diagnostics for *Leptospira spp.***

**Background:** Leptospirosis, caused by over 35 different species of pathogenic and intermediate *Leptospira* species, is one the most common zoonotic/environmental diseases in the world. *Leptospira spp.* are shed in animal urine and are capable of surviving in soil and water. Globally it is estimated that there are up to 500,000 severe cases of leptospirosis annually, although this is likely a severe underestimate due to non-specific clinical presentations, poor availability of reliable tests, and lack of surveillance systems. Cases of leptospirosis increase after flooding events, tends to affect individuals in economically poor areas, and is responsible for disproportionately high global burdens both economically and in disability adjusted life years for affected individuals. Due to climate change and the associated extreme weather events, it is expected that cases of leptospirosis will continue to increase at a high rate.

**Specific Research Area(s) of Interest:** The major research priorities areas for NCEZID are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of NCEZID will also be considered through this Omnibus solicitation. Research to address reducing health disparities and increasing health equity is strongly encouraged. Development of better diagnostic and environmental detection tools is critical to increase positive patient

outcomes and identify at risk populations.

**Examples of specific research areas of interest include, but are not limited to:**

- Development of new or enhanced diagnostics for *Leptospira spp.* including serological assays with better specificity/sensitivity and are easier to transfer to partners than current assays, rapid point of care diagnostics, and molecular assays capable of detecting intermediate pathogenic species in addition to pathogenic species.
- Develop diagnostic tests that can easily differentiate between species and/or serovars of *Leptospira spp.*
- Develop methods for better detection and genetic characterization of *Leptospira spp.* from environmental matrices.

**Impact:** Leptospirosis is vastly underreported in the US, and cases are likely to increase due to extreme weather events related to climate change. The proposed research should lead to practical solutions related to the detection of these pathogens in the environment and the effective diagnosis of disease in humans.

**Commercialization Potential:** Products related to the diagnosis and detection of *Leptospira spp.* will have significant commercial potential both in the domestic and international markets and will improve both surveillance and patient outcomes.

**(5) Vector Borne Diseases: Detection, Prevention, Diagnosis and Response**

**Background:** Bacterial and viral vector borne diseases are transmitted to humans primarily through vectors such as an infected mosquito, tick, or flea. Some of these diseases have long been present in the United States while others have recently emerged.

Vector-borne diseases are a major public health concern. Lyme disease causes over 300,000 estimated human illnesses annually in the U.S. tick-borne rickettsial diseases, such as Rocky Mountain spotted fever, ehrlichiosis, and anaplasmosis, are responsible for over 4,000 U.S. cases each year, including some that result in death. Dengue fever causes millions of cases worldwide, including thousands of cases in Puerto Rico each year. Outbreaks of arboviral diseases such as West Nile encephalitis and Chikungunya fever have been reported in recent years. Less common, but often deadly threats such as *Yersinia pestis* causes the ancient disease plague. Local plague outbreaks occur in the southwestern U.S., and it is a significant health threat in Africa and Asia.

**Specific Research Areas of Interest:** The goal of this project is to encourage research that will enhance prevention, detection, diagnosis, and response capabilities to vector borne diseases through funding innovative solutions that address the following:

- 1) Mitigate the spread and impact of vector borne diseases
- 2) Improve our ability to prevent, detect, and respond to outbreaks of vector borne diseases
- 3) Develop diagnostic tests to differentiate among vector borne diseases
- 4) Develop vaccines effective against vector borne diseases

**Impact:** Given the large number of individuals affected by these diseases, and the challenges to public health for their containment, improved detection through better diagnostic tests and improved prevention through vaccination would have a great impact on the health of the nation. The proposed research should lead to the development of practical solutions for the detection, prevention, and diagnosis of vector-borne diseases.

**Commercialization Potential:** The products and innovations developed through this process will have significant commercial potential and will improve public health and the healthcare system's response to vector-borne diseases.

## **(6) Antibiotic Resistant Healthcare-Associated Infections**

**Background:** Healthcare-associated infections (HAI) are a threat to patient safety. CDC provides national leadership in surveillance, outbreak investigations, laboratory research, and prevention of healthcare-associated infections. CDC uses knowledge gained through these activities to detect infections and develop new strategies to prevent healthcare-associated infections. Healthcare-associated infections (HAIs) can be found to effect 1 in 25 hospitalized patients on any given day in the United States, leading to an annual burden of 722,000 infections and 75,000 deaths. Meanwhile, among 18 antibiotic resistant (AR) organisms identified by CDC in 2013 as urgent, serious, and concerning threats, nearly half are primarily healthcare-associated. Whereas 1 in 7 HAIs in hospitals overall are caused by AR-threat bacteria, in some types of hospitals, AR-threat bacteria cause 1 in 4 infections. In all cases, HAIs caused by AR-threats are more difficult to treat and some are now untreatable. There are three broad, current strategies that clinicians and nurses need to employ to prevent these AR HAIs: following recommendations for preventing invasive device and surgical procedure-related infections, preventing cross-transmission of AR HAI pathogens, and practicing optimal antibiotic stewardship.

### **Specific Research Area(s) of Interest:**

The major research priorities areas for NCEZID are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of NCEZID will also be considered through this Omnibus solicitation. Research to address reducing health disparities and increasing health equity is strongly encouraged. The goals for the proposed research are to address antibiotic resistant healthcare-associated infections.

### **Examples of specific research areas of interest include, but are not limited to:**

- Development of novel diagnostics that either: 1) offer a more rapid and definitive diagnosis of whether a patient does or does not require an antibiotic (alternatively whether it is safe to stop an antibiotic), or 2) better detect (i.e., earlier, more rapidly, and more accurately) whether a patient is infected or colonized (and thereby may transmit) with an AR HAI pathogen.
- Novel therapeutics and preventatives based upon preservation or restoration of the human microbiome.
- Predictive surveillance analytics that harness genomic-scale (public) data for assessing potential trajectories and forecasting de novo risk analysis of bacterial strains/clonal types for epidemic spread, hypervirulence, and antibiotic resistance.

**Impact:** This research will lead to the development of practical and innovative solutions to address the matrix of complex problems caused by antibiotic resistant healthcare-associated infections.

**Commercialization Potential:** Successful and novel innovation that will reduce disease, disability, and death will have huge commercial potential across many markets.

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## NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)

### **Mission and Research Areas of Interest**

National Center for Environmental Health (NCEH) plans, directs, and coordinates a program to protect the American people from environmental hazards. We promote a healthy environment and prevent premature death, avoidable illness, and disability caused by non-infectious, non-occupational environmental and related factors. We are especially committed to safeguarding the health of vulnerable populations — such as children, the elderly, and people with disabilities — from certain environmental hazards.

NCEH encourages submission of research applications with innovative research technologies designed to reduce health disparities and promote health equity.

Please visit the NCEH web site at: <https://www.cdc.gov/nceh/>.

### **Description of Research Areas of Interest**

The major research priorities areas for NCEH are listed below. Investigator-initiated applications that have commercial potential that fall outside these topic areas but fall within NCEH's research mission will also be considered through this Omnibus solicitation. Research to address emerging health threats, health disparities, and health equity are strongly encouraged.

#### **(1) Tools or technologies to assess or estimate indoor air quality and health risks**

**Background:** Poor indoor air quality resulting from high levels of dust mite allergen, mold, and particulate matter less than 2.5 microns (PM<sub>2.5</sub>) is a well-established risk factor for development of respiratory diseases, including asthma. Because these agents are microscopic, occupants often do not know how to decrease exposure. Improved exposure assessment methods are an important tool in helping individuals decrease their exposure and prevent negative health outcomes resulting from poor indoor air quality related to these agents.

For this topic, NCEH has a specific interest in tools or technologies to assess indoor air quality related to particulate matter (PM<sub>2.5</sub>), allergens (such as those from dust mites), and mold (which contains allergenic and irritant components) implicated in the development or exacerbation of asthma; and in tools or technologies to assess building-related health risks that increase exposure to these agents.

**PM<sub>2.5</sub>:** Particulate matter less than 2.5 microns (PM<sub>2.5</sub>) is also microscopic and associated with asthma attacks. PM<sub>2.5</sub> is generated from smoke associated with cooking, hair dryers, and other smoke generating devices, including those in an occupational setting, and can accumulate to levels high enough to trigger asthma attacks without activating a smoke detector. An early warning system is needed before smoke detector activation. Such an early warning system could be connected to building systems (e.g., fans/filtration devices) which can turn on automatically to decrease PM<sub>2.5</sub> exposures prior to smoke detector activation to prevent the onset of asthma attacks. For additional information about indoor air triggers such as dust mites or mold, please

visit our web site at [https://www.cdc.gov/asthma/pdfs/home\\_assess\\_checklist\\_P.pdf](https://www.cdc.gov/asthma/pdfs/home_assess_checklist_P.pdf).

**Dust mites:** Exposure to dust mites can result in significant clinical illnesses including rhinitis, allergic asthma, atopic dermatitis, and conjunctivitis. The disparities in childhood asthma in the United States are well-known; approximately 16% of black children and 7% of white children have asthma (*CDC Vital Signs*). In the U.S., a population-based study found that 15-20% of participants were allergic to dust mites (Salo et al. 2011). Additional research showed that 25% of children with asthma have allergies to dust mites (Stevenson et. al., 2001). Furthermore, dust mite allergic sensitization varies by region, being more prevalent in the Southeastern U.S. (Salo et al. 2014). Although present in many residences and other buildings, dust mites are unnoticed because of their microscopic size and translucent bodies, making them difficult to detect and remove from homes, schools, and businesses.

**Mold:** In 2009, the World Health Organization concluded that early mold exposure was associated with the development of asthma in some children, particularly among children who may be genetically susceptible to asthma development, and that selected interventions that improve housing conditions can reduce morbidity from asthma and respiratory allergies. Mold allergy and exposure to mold has been found to be strongly associated with childhood emergency department visits in inner-city environments (Brosnan, 2013). Mold is also microscopic. During investigations of possible mold-related disease (e.g., allergy, asthma, and infections), costly and labor-intensive sampling by trained technicians and analysis in laboratories can delay action for mold remediation due to the misidentification of “mold-like” substances which are not mold (e.g. soot, rust, and algae).

Building related risk factors can contribute to poor health outcomes from asthma triggers: Several well-established housing characteristics are associated with poor indoor air quality. For example, age of housing, presence of basements, type of housing structure, number of stories/floors, and presence of crawl spaces have been associated with greater risk of mold exposure. Although the American Housing Survey is a large population-based survey of the U.S., it only conducts a sample. Only tax assessor data contains this type of information for each building across the country. With tax assessor data (not centrally managed but managed by each county or state), geographic information system (GIS) mapping can be used to overlay these data with health data to better elucidate the relationships and building-related risk factors between indoor air quality and adverse health outcomes. NCEH is interested in better understanding how the gentrification of neighborhoods can modify such relationships between housing-related factors and adverse health.

**Project Goal:** The goal for the proposed research is to develop tools or technologies to assess indoor air quality related to PM2.5, dust mite, or mold exposure, and to develop data-linkage platforms to identify building-related features that are associated with increased risk for poor indoor air quality from buildings within the U.S.

Examples of specific research areas of interest include, but are not limited to, the development of an:

- Early warning system integrated with building systems (e.g., fans/filtration devices) to automatically detect smoke related PM2.5 levels prior to smoke detector activation.
- Application to alert individuals that they are in a high-risk dust mite area.
- Application that can view mold-like substances on a surface, and determine if the substance is mold (e.g., using computerized image analysis).
- Machine learning capable data-linkage platform that can extract building information from tax assessor datasets and enable granular assessments of building-related risk factors from data spanning several years.

***Impact:*** Asthma resulting from indoor air exposures to allergens and particulate matter is a significant public health concern, resulting in acute and chronic clinical disease for millions of Americans.

Innovative technologies to rapidly detect and prevent these exposures would have a beneficial impact on public health, especially for underserved populations experiencing residential or occupational housing inequities and at increased risk for exposure to indoor air pollution. The technologies sought for development have the potential for commercial application across many markets, including residential and occupational settings, schools, and healthcare facilities.

A building air quality data-linkage platform can enable more granular assessments of building-related risk factors that decrease indoor air quality and subsequently affect health. More accurate assessments of building-related risk factors will enable future researchers to better understand place-based determinants of health impacting asthma and many other poor health outcomes (e.g., cardiorespiratory disease) resulting from exposures in residential and/or occupational settings.

***Commercialization Potential:*** Commercial application of this technology could allow state and local jurisdictions, businesses, and public health practitioners address housing related environmental justice issues in a focused manner instead of only using broad levels of building characteristics (e.g., multi-family homes vs. single-family homes).

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## **NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD, AND TB PREVENTION (NCHHSTP)**

### **Mission and Research Areas of Interest**

NCHHSTP is committed to our vision of a future free of HIV/AIDS, viral hepatitis, STDs, and TB. We are responsible for public health surveillance, prevention research, and programs to prevent and control HIV and AIDS, other STDs, viral hepatitis, and TB. NCHHSTP's Strategic Plan

articulates a vision, guiding principle, and overarching goals and strategies to influence and enhance our programs. The three overarching goals highlighted in this plan are to decrease:

- incidence of infection,
- morbidity and mortality, and
- health disparities.

Every year, millions of Americans are infected with HIV, viral hepatitis, STDs, or TB, and tens of thousands die from their infection. Most of these infections share commonalities, from modes of transmission to demographic, social, and economic conditions that increase risk. As a prevention leader, NCHHSTP focuses on high impact prevention and control efforts to reduce incidence, morbidity, mortality, and health disparities due to these infections.

Please visit the NCHHSTP website at: <http://www.cdc.gov/nchhstp/>.

## **Description of Research Areas of Interest**

### **(1) Improved Diagnostic Tests for HIV, STDs, Hepatitis, and TB**

***Background:*** For many individuals infected with HIV, Hepatitis C, STDs and TB, they do not receive timely diagnosis due to stigma associated with these infections. Improving diagnostic technology and offering alternatives that can be done at the point of care or self-testing has the potential to decrease morbidity and transmission. For individuals that are at risk and uninfected, it allows them to focus on prevention. For those that are infected, treatment can be started earlier. Furthermore, since many of the infections share common routes of transmission or have high rates of infections in specific populations, there is the potential for overlapping infections also known as syndemics.

Whereas there is tremendous value in testing and diagnosis for each of the described diseases, some at risk individuals are never tested or do not receive their tests results and often times are only tested for one of the diseases when testing for a combination of the diseases would be more beneficial both for the individual and for public health. Prognostic tests (e.g., viral load, drug resistance monitoring) also play an important role in improving health outcomes for infected individuals.

***Specific Research Areas of Interest:*** The major research priorities areas for NCHHSTP are listed below. Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of NCHHSTP will also be considered through this Omnibus solicitation. Research to address reducing health disparities and increasing health equity is strongly encouraged.

The major goal of the project is development of diagnostic reagents, tests or testing platforms, that will further improve diagnosis or monitoring of HIV hepatitis C, syphilis, gonorrhea or TB. The specific area of interest is innovative approaches or novel technology that would allow for easier screening for or diagnosis of HIV hepatitis C, syphilis, gonorrhea or TB alone or in any combination using a single test device or platform.

**Examples of specific research areas of interest include, but are not limited to:** The preferred test format or technology would facilitate testing that allows for rapid results (preferably less than one hour), is affordable (comparable to currently available tests) and can be performed at the point of care or by an individual (self-test). Tests that include an option for self-collection for submission to a laboratory are also desired. Likewise, the ability to combine detection and markers for drug resistance gonorrhea, and TB specifically) is highly desired as it would allow for better treatment outcomes and reduce the spread of drug resistant pathogens.



***Impact:*** It is known that early diagnosis and treatment of HIV infection can improve health outcomes for individuals infected with HIV. Furthermore, such testing has the potential for decreasing transmission of HIV. Likewise, improved diagnosis of HCV can lead to curative treatment. For syphilis, improved diagnostic tools have the potential to decrease congenital syphilis and promote timely treatment to prevent spread to sexual partners. Improved TB and gonorrhea testing that includes easy detection of drug resistance is important to prevent the spread of drug resistant strains and improve treatment. Improving diagnosis of all of these pathogens has a potential for a significant decrease in morbidity. Faster turnaround times, lower cost, and more efficient detection would be highly impactful for these individuals, their partners and the community.

***Commercialization Potential:*** Diagnostic reagents, tests or testing platforms, that will further improve diagnosis or monitoring of HIV, hepatitis C, syphilis, gonorrhea or TB, would be in great demand by the healthcare and public health systems as well as other sectors engaged in using diagnostics to treat or prevent transmission in impacted populations.

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## **NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)**

### **Mission and Research Areas of Interest**

The mission of the National Center for Immunization and Respiratory Diseases (NCIRD) is the prevention of disease, disability, and death through immunization and by control of respiratory and related diseases. NCIRD balances its efforts in the domestic and global arenas as well as accommodates the specific needs of all populations at risk of vaccine preventable diseases from children to older adults. Research to address reducing health disparities and increasing health equity is strongly encouraged.

Please visit the NCIRD website at: <http://www.cdc.gov/ncird/>.

### **Description of Research Areas of Interest**

## (1) Prevention and Diagnosis of Acute Respiratory Infections in the US and Globally

**Background:** Acute respiratory infections kill an estimated 3.9 million people annually and in developing countries are the leading cause of mortality in children under 5 years of age. Specific respiratory virus infections such as influenza, SARS-CoV-2, and respiratory syncytial virus, are major contributors to this burden of disease, as are other respiratory bacterial and viral pathogens. Respiratory virus infections are frequent events in all age groups and impose a substantial burden on social and healthcare delivery systems.

**Specific Research Areas of Interest:** The goal of this research includes, but is not limited to, activities that support the development and evaluation of tools for: 1) the prevention of acute respiratory infections such as pneumonia, influenza, COVID-19, and Legionnaire's disease, 2) rapid recognition and containment of outbreaks, and 3) advanced diagnostic technologies including point-of-care testing, advanced molecular detection, and whole genome sequencing.

**Impact:** This research will lead to the development of practical solutions for the prevention and diagnosis of vaccine preventable diseases that have a substantial impact on the economy, health, and wellbeing of society. The goal of the research supported through this mechanism is expected to begin shifting viral and bacterial infections from common occurrences to rare events and to reduce the disproportionate burden of COVID-19 on populations at increased risk for infection, severe illness, and death.

**Commercialization Potential:** The innovative technologies and solutions developed through this program will make it possible to improve the public health and healthcare system's response in a variety of settings, thus making the commercialization potential unlimited.

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# NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC)

## **Mission and Research Areas of Interest**

For 30 years, CDC's National Center for Injury Prevention and Control (NCIPC) has helped protect Americans from injuries and violence. We are the nation's leading authority on injury and violence. We study violence and injuries and research the best ways to prevent them, applying science and creating real-world solutions to keep people safe, healthy, and productive. NCIPC will prioritize funding meritorious applications that address the NCIPC program topics listed in this program announcement. NCIPC may also consider meritorious applications that address current NCIPC research priorities.

To learn more about NCIPC, please visit the NCIPC website at: <http://www.cdc.gov/injury/index.html>.

## **Description of Research Areas of Interest**

NCIPC encourages submission of research applications with innovative research technologies designed to reduce health disparities and promote health equity.

The major research priorities areas for the NCIPC are listed below. Investigator initiated applications that have commercial potential that are outside these topic areas but within the research mission of NCIPC will also be considered through this solicitation. Research to address emerging health threats, health disparities, and health equity are strongly encouraged.

To learn more about NCIPC research priorities, please visit our web site at: <https://www.cdc.gov/injury/researchpriorities/index.html>.

### **(1) Prevention and Management, and Recovery of Traumatic Brain Injury**

***Background:*** There were nearly 70,000 traumatic brain injury (TBI)-related deaths in 2021 and more than 200,000 TBI-related hospitalizations. TBIs affect how the brain works and can range from mild concussions to serious and debilitating injuries with long-term effects. They are caused by a bump, blow, or jolt to the head or a penetrating injury (e.g., a gunshot) and are often the result of falls, firearms, motor vehicle crashes, or assaults. While TBIs affect individuals of all ages, research suggests that some individuals may be at greater risk for experiencing a TBI and more severe consequences of a TBI. Individuals at higher risk often include racial and ethnic minorities, service members, people living in rural communities, and survivors of intimate partner violence, among others.

The trajectory of recovery from a TBI is influenced by multiple factors, including the overall severity of the injury, number of prior TBIs, and receiving an appropriate diagnosis, referrals, and tailored care. Individuals are generally eager to return to prior activities following a TBI. However, there can be considerable complexity in decision-making around when to return to school, work, physical activity, driving, or other daily tasks. Careful monitoring and tracking of symptoms can help inform this decision-making, as well as having access to easy-to-use evidence-based resources and supports to guide one's recovery path. Additionally, due to symptoms experienced and uncertainty around recovery timeline, TBI recovery can be particularly challenging from not only a physical health perspective but also a social, emotional, and mental health perspective (e.g., anxiety, sadness). Therefore, ensuring that strong, active support networks exist for individuals with TBIs is a critical component of the recovery process.

***Project Goal:*** CDC is interested in research to develop technology that can assist persons with a TBI in better assessing when they can return to normal activities, including school, work, physical activity, driving, and/or other daily activities. The technology can help improve understanding and confidence among individuals with a TBI in tracking their path to recovery, as well as preventing future TBI.

The technology could aid those who have experienced a TBI by helping them better understand what to expect, track their symptoms throughout their recovery to help inform decision-making around returning to activities, access recommendations each step of the way to guide them towards recovery and reintegration in activities, and access support networks or linkage to support networks to help manage social, emotional, and mental health during recovery. Knowledge of what to track and look for at each step of the recovery process, support tips and information to help guide individuals (including consideration of when to transition from rest to light, moderate, or full activity, how to handle recovery delays, and when to seek additional healthcare), and connections to active supports and communities to ensure care of not only physical but also social and emotional health during the recovery period are critical needs. The technology can also help prevent future, repeated TBI by providing individuals with information and tools centered around TBI risks and effective prevention approaches.

Given disparities in TBI, the technology should consider tailoring and framing to populations at highest risk. These populations could include, but are not limited to, military service members and veterans, racial and ethnic minorities, people living in rural communities, survivors of intimate partner violence, and people of lower incomes and without access to healthcare.

For Phase I, the awardee is expected to develop, and beta test new technology designed to support individuals on their road to recovery from a TBI. The technology should be intuitive and easy to use.

***Impact and Commercialization Potential:*** The availability of technology that can ease one's road to recovery from a TBI can help improve recovery timelines and improve quality of life and social, emotional, and mental health. Such technology can also help individuals better understand, track, manage, and recover from their symptoms and reintegrate into normal activities, including school, work, physical activity, driving, and other daily activities. Additionally, the availability of technology could assist in reducing health disparities among vulnerable populations who tend to have worse health outcomes (a greater likelihood of dying from a TBI or living with long-term problems that resulted from the injury). Development of this technology has commercial viability. Commercial applications of this technology may be of interest to adolescents, adults, caregivers, healthcare providers, health insurance companies, and youth sports personnel, among others.

## **(2) Technological Innovations to Reduce Deaths and Injuries from Motor Vehicle Crashes**

***Background:*** Motor vehicle crashes are a leading cause of death among those aged 1-54 years in the United States, killing over 40,000 people every year and injuring 3 million more. Motor vehicle crashes can result from a single or combination of environmental, human behavioral, and vehicle-related risk factors including hazardous road conditions, driving too fast for the environment, driver perception deficits, non-compliance with vehicle safety devices, impaired driving, lack of seat belt use, lack of helmet use, distracted or drowsy driving, and sub-optimal vehicle performance. Reducing any of these risk factors can lower the likelihood of a crash and increase the chance of survival in the event of a crash.

Adaptive technologies can generate feedback loops about the road and environment, driver fitness, and vehicle performance. Applications of these adaptive technologies in both private and commercial vehicles can reduce risks associated with motor vehicle crashes. Currently, there are a limited number of adaptive technologies to warn drivers of potential dangers associated with driving; most of these technologies focus on vehicle related performance (e.g., collision warning, electronic stability control, and lane departure warning). Innovative adaptive technologies are sought that can assist in alerting drivers to risks associated with the road or environment and vehicle performance, and that can facilitate drivers to modify personal risk behavior, including impaired or drowsy driving. These adaptive technologies can result in the development of tools or systems that will reduce the likelihood and severity of motor vehicle crashes and assist drivers in making potentially life-saving decisions more quickly and more intuitively.

***Project Goal:*** CDC is interested in research to address the development of improved

technologies that have the potential to further reduce motor vehicle crashes and resulting injuries to all road users.

These technologies can address driver risks such as excessive speed, distracted driving, impaired driving, drowsy driving, non-compliance with use of vehicle safety equipment (e.g., seat belts), environmental conditions (including road quality), vehicle performance and other factors that may impact driving. Technologies could also address risks to individuals walking, biking, riding, or rolling, such as crowdsourcing information on unsafe infrastructure (e.g., sidewalk gaps, unsafe walking surfaces and compliance with the Americans with Disabilities Act). For Phase I, the awardee is expected to develop and pilot test new technology designed to reduce motor vehicle crashes and resulting injuries. Testing could also consider and explore acceptability of the technology to road users.

***Impact and Commercialization Potential:*** The availability of technologies to reduce motor vehicle crashes and resulting injuries can save lives. Technologies that reduce motor vehicle crashes and resulting injuries can help improve health equity and reduce injury disparities among vulnerable road users. Development of these technologies has commercial viability. Commercial applications of this technology might be of interest to motor vehicle manufacturers, insurance companies, clinicians, health systems, departments of transportation, parents of young drivers, and all road users.

### **(3) Electronic Tools to Assist Older Adults at Risk for Falls**

***Background:*** Unintentional falls are the leading cause of fatal and nonfatal injuries in older adults aged 65 years and older. Falls result in 3 million emergency department visits and more than 900,000 hospitalizations each year. About 38,000 older adult deaths occur each year because of a fall. This risk of falls and their consequences is not equally distributed across the population. Research indicates that fall risk is highest among adults of older ages (e.g., 80+), American Indian/Alaska Native and White non-Hispanic populations, individuals with numerous chronic health conditions (e.g., depression, diabetes, cardiovascular disease, stroke), and those with neurological disorders (e.g., dementia, Parkinson's disease). Falls often lead to reduced mobility and loss of independence; therefore, reducing fall risk is conducive to maintaining independence.

An example of a resource for information about falls prevention is [CDC's Stopping Elderly Accidents, Deaths, and Injuries \(STEADI\) initiative](#). CDC developed the STEADI initiative based on the American and British Geriatric Societies Guideline for the Prevention of Falls in Older Persons to provide training, resources, and tools for healthcare providers to use to incorporate older adult fall prevention into routine clinical care. STEADI has three core components – SCREEN older adults at least annually to determine who is at risk for a fall, ASSESS those at risk to determine their modifiable risk factors, and INTERVENE by recommending evidence-based strategies for each identified risk factor. Modifiable risk factors (and associated strategies to address them) include strength and balance limitations (physical therapy); medications with side effects that increase risk (medication management); vision problems (vision exam), foot problems (podiatrist exam), orthostatic blood pressure (medication management or referral to a specialist); home hazards (home assessment with an occupational therapist), and comorbidities (medication management or referral to a specialist).

A fourth potential core component is patient FOLLOW-UP. Older adults are more likely to follow these recommendations with continuous follow up from their healthcare provider and when receiving reminders and continuous ongoing support (e.g., from their network of support persons and/or caregivers). Older adults are also more likely to follow recommended fall prevention activities when the activities are affordable and easily accessible. Finally, recommendations utilizing a positive framing regarding preserving mobility and thriving as we age can be particularly effective (e.g., CDC's "Still Going Strong" campaign). Technologies targeted at older adult healthcare providers, as well as older adults and their families, caregivers, and support persons may help facilitate long-term uptake of interventions and strategies to prevent falls and

maintain mobility within a positive framing.

***Project Goal:*** CDC is interested in research to develop technology that will help healthcare providers incorporate STEADI-based fall prevention into their clinical practice and/or support older adults and their families, caregivers, or support persons in understanding and supporting active implementation of recommended strategies to reduce older adults' fall risk, maintain mobility, and support healthy aging.

One way this can be accomplished is through technology that incorporates elements of an evidence-based program, such as those described in CDC's STEADI tools and resources and inspired by a positive, optimal mobility approach such as those used in CDC's Still Going Strong campaign or CDC's MyMobility Plan tools. For example, the technology could support healthcare providers' use of the STEADI algorithm that guides them through the three core components.

Alternatively, the technology could integrate STEADI, Still Going Strong, MyMobility Plan, or other patient education materials and resources to educate older adults and their families, caregivers, and support persons about falls and how to prevent them, maintaining strength and health as one ages, and adhering to fall prevention recommendations.

Given disparities in falls risk, the technology should consider tailoring and framing to populations at highest risk, as noted above. For Phase I, the awardee is expected to develop and beta test the technology. The technology should incorporate applicable healthcare information privacy regulations, be intuitive and easy to use by the target audience, and include an interface designed with the target audience in mind.

***Impact and Commercialization Potential:*** The availability of a technological tool to assist clinicians or older adults, their families, and support persons in preventing falls and maintaining mobility can help ensure that healthcare provider recommendations and evidence-based strategies are followed. By facilitating fidelity to recommendations and improving communication about fall risk, healthy aging, and prevention between older adults, families, and providers the expected public health benefit is a reduction in older adult falls and increased support for healthy aging.

Development of a technological tool that reduces risk for older adult falls has commercial viability. Commercial applications of this technology may be of interest to older adults and their families, healthcare providers, community support staff, health insurance companies, and other stakeholders invested in preventing older adult falls and supporting healthy aging.

#### **(4) Innovative Technologies to Help Prevent Drug Overdose**

***Background:*** The national drug overdose crisis continues to evolve in the United States, causing increasing numbers of deaths and warranting innovative interventions. In 2022, over 107,000 people died from drug overdoses and 76% of those deaths involved opioids. Over 26% of overdose deaths in 2022 involved cocaine, and almost one-third (32%) involved psychostimulants with abuse potential (e.g., methamphetamine). Further, recent data suggest that overdoses involving multiple substances are increasing. Given the evolving nature of the overdose crisis, there is a need for innovative technological approaches to support the prevention of drug overdose. These technologies can focus on: 1) using data to inform action (i.e., linking various data platforms, including those that monitor and track nonfatal or fatal drug overdoses or emerging drug threats to inform overdose prevention and response efforts; 2) developing or implementing digital interventions to deliver drug overdose prevention); 3) helping people in need of substance use treatment or harm reduction services identify and access services; and 4) developing and implementing applications or platforms to monitor the provision of care and harm reduction services or materials or track usage and/or outcomes.

Innovative solutions are needed to support new opportunities to effectively leverage technology and data systems to improve drug overdose prevention and response efforts, link and retain people who use drugs to care and harm reduction services and monitor the provision of harm reduction services or materials and track usage and outcomes of these services. To support these objectives, we are soliciting proposals to create innovative and user-friendly, electronic tools, applications, or technologies that address at least one of the following prevention activities:

1. Using data to inform action: Aggregate and synthesize information from various data sources that track nonfatal or fatal drug overdoses or document emerging drug threats (e.g., toxicology or drug seizure data) to inform and implement overdose prevention and response efforts (e.g., using data to identify geographical “hotspots” that can benefit from naloxone distribution, fentanyl test strips, or overdose prevention campaigns).
2. Develop or implement digital drug overdose prevention: Digitally deliver overdose prevention materials (e.g., information on how to recognize signs and symptoms of drug overdose, how to respond to a suspected drug overdose, where to obtain naloxone) using innovative technology.
3. Helping people in need of substance use treatment or harm reduction services identify and access services: Develop or implement a mechanism for people who use drugs (PWUD) and their family or friends to identify and access local substance use disorder (SUD) treatment or harm reduction support services. This could include developing an application or tool to help identify providers based on geography or services provided or help identify and remedy barriers to accessing services (e.g., transportation, childcare services, etc.).
4. Developing and implementing applications or platforms to monitor the provision of care and harm reduction services or materials or to track usage and/or outcomes: To better monitor the provision of care and harm reduction services or materials to clients, develop an innovative solution to monitor metrics on service delivery and uptake or to track usage and/or outcomes (e.g., linkage and retention or use of services).

References:

1. Spencer MR, Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2002–2022. NCHS data brief, no 491. Hyattsville, MD: National Center for Health Statistics. 2024.

**Specific Area of Interest/Project Goal(s)**: CDC is interested in research that aims to develop innovative technologies that will leverage data to inform overdose prevention, develop or implement digital overdose prevention materials, link people who use substances to effective substance use treatment or harm reduction services, and develop and implement strategies to monitor the provision of care and harm reduction services and track usage and/or outcomes of these services. The technology should use information relevant in local communities. For example, the technology could tailor available services options including by location and current capacity and automate referral processes to local services to provide PWUD a seamless process for finding, contacting, and accessing services. Other examples include incorporating current characteristics of the local epidemic into linkage messaging or a menu of locally available recovery support services such as transportation, employment services, or housing support. Tracking usage and/or outcomes could help enhance the technology over time by compiling data regarding most used services, gaps in available services, reason services are sought, and outcomes of specific services.

The technology should reflect feasibility and acceptability for the population it is intended to serve: PWUD. Therefore, the technology should be accessible for PWUD in the local area.

The expected research outcome is the development of technology that will ultimately better track and respond to overdoses. Projects will help tailor and deliver prevention and response efforts, connect PWUD to locally available SUD treatment, harm reduction, and recovery support services, or help service providers (e.g., SUD treatment providers or harm reduction services) monitor the provision or uptake of services or track usage and/or outcomes (e.g., linkage and retention in care).

For Phase I awards, the recipient is expected to develop and beta test the new technology(ies) with the relevant population (e.g., PWUD and at least one type of local service: SUD treatment, harm reduction services, recovery support services). Recipients must attend to appropriate protections related to confidentiality, personally identifiable information, health information, and SUD privacy regulations associated with these technologies, such as those that apply to sharing protected health data across systems or any stigma associated with using the technology. The technology must be intuitive and easy to use.

***Impact:*** The availability of technological tools to assist those at risk for drug overdose within communities can help better implement effective overdose prevention and response, and ensure that needed referrals, services, and follow-up care are received and that linkages are made in a timely manner to effectively prevent immediate risks. By improving access to medical and non-medical support services and near real-time data, the expected public health benefit is reduced potential for drug overdose, and increased linkage to SUD treatment, harm reduction services, and recovery support services that can reduce the risk of drug overdose, and a more accurate understanding of services delivered.

Some populations, communities, and geographic areas are disproportionately impacted by overdose and can be considered for tailored programs and interventions based on associated risk for overdose or disparities in access to harm reduction services and SUD treatment. Further, having a SUD is a chronic health condition, yet individuals with SUD face barriers to accessing the care they need due to stigma and other factors. Moreover, PWUD may be more likely to have intersecting characteristics (e.g., experiencing homelessness, being involved in the justice system) that may be associated with poor health outcomes (such as overdose death), either by having an increased likelihood of drug use or a reduced likelihood of receiving care if they develop an SUD. Such characteristics may also impact accessibility to some technologies, and solutions must incorporate meeting PWUD where they are to have the most reach. The proposed technologies have the potential to reduce barriers to receiving overdose prevention and care among people who use drugs, including those who have a SUD, thereby reducing health disparities among this important population. Research suggests that some populations may have a greater risk for experiencing disproportionate burden of drug overdose or experiencing adverse outcomes related to drug use due to social determinants of health, indicating a potential opportunity to intervene and support such populations. The development of innovative technologies for overdose prevention or to support linkage to care among PWUD who experience a disproportionate burden of overdose or experience adverse outcomes related to drug use can help prevent drug overdose and simultaneously improve health equity.

The availability of technological tools to assist those at risk for drug overdose and those working to prevent and respond to overdose within communities can better ensure that needed referrals, services, and follow-up care are received and that information is shared in a timely manner to effectively prevent immediate risks. By improving access to medical and non-medical support services and near real-time data, the expected public health benefit is increased linkage to support services, harm reduction services, and/or data and resources that can reduce the risk of drug overdose.

Some populations, communities, and geographic areas are disproportionately impacted by overdose and can be considered for tailored programs and interventions based on associated risk for overdose or disparities in access to harm reduction services and substance use treatment. Further, having a substance use disorder (SUD) is a chronic health condition, yet individuals with SUD face barriers to accessing the care they need due to stigma and other factors. Moreover, PWUD may be more likely to have intersecting characteristics (e.g., experiencing homelessness, being involved in



the justice system) that may be associated with poor health outcomes (such as overdose death), either by having an increased likelihood of drug use or a reduced likelihood of receiving care if they develop an SUD.

The proposed technologies have the potential to reduce barriers to receiving care among people who use drugs, including those who have a SUD, thereby reducing health disparities among this important population. The development of innovative technologies to support linkage to care among PWUD and population subsets of PWUD (e.g., persons who have previously experienced an overdose; persons experiencing homelessness; justice-involved populations recently released from incarceration; those disadvantaged by economic instability, limited education attainment, access, and quality, and/or limited health care access and quality), can help prevent drug overdose and simultaneously improve health equity.

**Commercialization Potential:** Commercial applications include technological tools developed, for example to link people at risk for drug overdose to treatment or other services. Tools to create connections and opportunities for data and resource sharing between PWUD and relevant services also have commercial viability. Commercial applications of this technology may be of interest to those at risk for overdose and their families, community support programs and staff, health insurance companies, SUD treatment providers, harm reduction providers and other stakeholders invested in preventing drug overdose.

## **(5) Innovative Technology or Media to Prevent Violence Affecting Children/Youth**

**Background:** Violence is a significant public health problem in the United States. In 2021, more than 26,000 people died from homicide. Far more people experienced nonfatal violence. For example, more than 1.4 million people were treated for nonfatal injuries from assaults in U.S. emergency departments in 2021. Experiencing violence has a profound impact on lifelong health, opportunity, and well-being. Violence starts early in life. In 2021, there were an estimated 4.0 million referrals to child protective services for child abuse or neglect involving an estimated 7.2 million children. In addition to child abuse and neglect, other forms of violence impacting children and youth, include sexual violence, teen dating violence, youth peer violence, youth/parent suicidal behavior, and exposure to adult intimate partner violence.

Adverse Childhood Experiences (ACEs) are potentially traumatic events that occur in childhood (0-17 years). ACEs include experiencing violence, abuse, or neglect; witnessing violence in the home or community; or having a family member attempt or die by suicide. Also included are aspects of the child's environment that can undermine their sense of safety, stability, and bonding such as growing up in a household with substance use, mental health problems, or instability due to parental separation or household members being in jail or prison. Common risk factors for ACEs and violence can also start in early childhood and continue throughout the lifespan. They go beyond individual-level factors to include family and peer relationships and other influences from schools, the community, and society. Social determinants of health are the circumstances in which people are born, grow up, live, work and age, and the systems put in place to deal with illness. These circumstances are in turn shaped by a wider set of forces: economics, social policies, and politics (see [https://www.who.int/health-topics/social-determinants-of-health#tab=tab\\_1](https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1)). Social determinants of health (e.g., concentrated poverty, structural racism, high rates of unemployment and community violence, limited access to high-quality education and/or limited access to affordable, high-quality childcare) are key drivers of health inequities among communities of color and place them at a greater risk for experiencing violence.

The focus of CDC's violence prevention work includes the following principles: 1. Advancing economic, gender, and racial equity, 2. Enhancing positive relationships and environments, 3. Addressing factors that cut across multiple forms of violence, and 4. Prioritizing efforts that create societal- and community-level impact.

By focusing on activities that prevent multiple forms of violence, communities can achieve the greatest impact and increase scalability of their prevention strategies. Additionally, these prevention efforts are ideally

designed to use resources more effectively and to better address inequities by focusing on the needs of populations at greatest risk. To help communities make decisions about violence prevention strategies, CDC has released a series of Resources for Action documents that describe the best available evidence for violence prevention (see <https://www.cdc.gov/violenceprevention/communicationresources/pub/resource-for-action.html>). Many of the strategies in the Resources for Action documents are relevant to multiple forms of violence, including multiple ACEs (see [https://www.cdc.gov/violenceprevention/pdf/ACEs-Prevention-Resource\\_508.pdf](https://www.cdc.gov/violenceprevention/pdf/ACEs-Prevention-Resource_508.pdf) for strategies drawn from the Resources for Action documents that are relevant to ACEs).

Broader benefits could be achieved from wider **dissemination of effective violence prevention strategies** through innovative media and communication technology (e.g., mobile applications, social media, games, and Internet-based interventions). Media and communication technology also create the opportunity for the **development of new prevention approaches** based on what is known about violence risk and protective factors and strategies that work in traditional settings. Innovative media and communication technology can play an important role in effectively reaching populations at greatest risk and potentially facilitate changes at multiple levels (individual, relationship, community); however, research is needed to guide the development of technological applications for prevention strategies.

**Project Goal:** CDC is interested in research to develop innovative technology or media, such as applications for mobile devices, social media, games, or Internet-based interventions to prevent multiple forms of interpersonal violence (e.g., child abuse and neglect, youth violence, sexual violence, and intimate partner violence) and other ACEs affecting children or youth, particularly among groups or communities that are disproportionately impacted by multiple forms of violence and poor social determinants of health (see <https://www.cdc.gov/injury/researchpriorities/index.html>).

This includes, but is not limited to, new media and communication technology to do the following: increase the accessibility of prevention approaches, modify norms about violence and bystander behavior, enhance education and support for young children and their families, reduce stigma and barriers to help seeking, and/or enhance young people's skills and relationships to reduce risk for multiple forms of violence. Additionally, CDC is interested in new media and communication technology that could increase the adoption of community-level violence prevention strategies and strategies that improve social determinants of health in communities disproportionately affected by violence (e.g., housing stability, food security, education and employment opportunities, access to quality and affordable healthcare, etc.).

The widespread use of smartphone applications, social media, and wearable technology also provides unique opportunities for the broader dissemination, implementation, and evaluation of evidence-based prevention strategies to significantly reduce violence, such as strategies identified in the violence prevention technical packages used in real world settings. Applicants are encouraged to develop technology or media that could help address poor social determinants of health that contribute to inequities in rates of violence experienced by racial/ethnic and other groups or communities that are disproportionately impacted by multiple forms of violence, ACEs, and/or associated risk factors.

The prototype (e.g., developing innovative technology or media) should be informed by prior research about violence risk and protective factors and/or evidence-based prevention strategies and through consultation with subject matter experts in the form(s) of violence and the technology or media selected. The awardee should describe the following: the intended audience and the type(s) of violence addressed; goals for the product at the individual, family/relationship and/or community level(s); the process through which the technology or media is expected to work and the measurements and key performance indicators for tracking progress toward the goals; the expected impacts on violence and violence-related inequities; the functionality and actions for users to take; the estimated costs and logistics of scalability; a description of potential barriers to implementation; and any evidence for the potential benefits from prior research.

***Impact:*** The results from this research will have substantial implications for either the creation of innovative prevention approaches or for enhanced opportunities to disseminate existing evidence-based strategies, both of which have the potential to leverage technology to improve social determinants of health, increase health equity, and substantially reduce multiple forms of violence (e.g., child abuse and neglect, youth violence, sexual violence, and intimate partner violence) and other ACEs. Technological or media innovations that show effectiveness in preventing violence affecting children and youth and communities and groups disproportionately impacted by violence would have the potential for a range of commercial applications.

***Commercialization Potential:*** Depending on the nature of the strategy, the intended audience, and the costs/logistics of scalability, the product could be in demand by healthcare systems, school systems, colleges and universities, youth serving organizations, law enforcement, public health agencies, community groups and organizations, parents, and their children.

Visit the NCIPC homepage for more information on NCIPC's research program areas at <http://www.cdc.gov/injury/index.html>.

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## **NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)**

### **Mission and Research Areas of Interest**

The National Institute for Occupational Safety and Health (NIOSH) is part of the U.S. Centers for Disease Control and Prevention (CDC). It has the mandate to assure "every man and woman in the Nation safe and healthful working conditions and to preserve our human resources." NIOSH has more than 1,500 employees from a diverse set of fields including epidemiology, medicine, nursing, industrial hygiene, safety, psychology, chemistry, statistics, economics, and many branches of engineering. NIOSH works closely with the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration in the U.S. Department of Labor to protect American workers. [=

For additional information about NIOSH, please visit their web site at: <http://www.cdc.gov/niosh/programs>. The major research priority areas for NIOSH are listed below.

Investigator initiated applications that have commercial potential that fall outside these topic areas but fall within the research mission of the NIOSH will also be considered through this Omnibus solicitation. Research to address emerging health threats, health disparities, and health equity are strongly encouraged.

NIOSH typically supports Phase I awards at the maximum allowable total cost as stated in the funding announcement. However, in most cases Phase II applications are limited to a maximum total cost of \$1M for the two-year period of performance.

## **(1) Control Technology and Personal Protective Equipment for High-Risk Occupations**

**Background:** Personal protective equipment (PPE) protects workers from death and disabling injuries and illnesses as well as from the specific threats of exposures to certain airborne biological particles, chemical agents, nanomaterials, splashes, noise exposures, fall hazards, head hazards, and fires. It is estimated that 20 million workers use PPE on a regular basis to protect them from job hazards and a total of 135,000 workers potentially could benefit from the use of PPE ([Worker Health Chartbook 2004](#)).

Engineering controls include substitution of a safe material for a hazardous one, design changes to equipment, or modification of work methods to eliminate or reduce hazards. Research is needed to develop and evaluate control strategies and personal protective equipment for specific hazards and to assure their practicality and usability in workplaces in all of the high-risk industrial sectors.

For additional information about NIOSH PPE and Engineering control programs, please visit their web site at: <http://www.cdc.gov/niosh/programs/ppt/> and <http://www.cdc.gov/niosh/programs/eng/>.

### **Examples of specific research areas of interest include, but are not limited to:**

Conduct research on the ability of existing containment and control strategies to prevent releases and potential human exposures to engineered nanomaterials.

Develop innovative engineering control approaches and technologies for reducing respirable crystalline silica exposures for workers involved in manufacturing, finishing, and installing natural and engineered stone countertops.

Research should be conducted to reproduce the original human performance data using modern advanced technology and a pool of subjects that represents the current American workforce. Additionally, the scope of the subject pool can be expanded to encompass all workers. The generated data would be used to confirm or adjust the parameters used for respirator approval testing, as well as aid in the development of respirator standards used for all workers including younger (children) workers in high risk occupations.

Conduct research to evaluate the effectiveness of personal protective equipment in protecting workers against exposure to engineered nanomaterials. Provide data to fill knowledge gaps and support guidance for the selection and use of gloves and protective garments to prevent exposures. Respiratory protection research needs to be extended to a broad range of engineered nanomaterials.

Develop a heads-up display coupled with a personal noise exposure monitoring system. Personal noise alert "badges" and personal noise dosimeters exist, but do not have an effective way to alert the user immediately when a noise hazard occurs. A system that displays a warning within the user's visual field (via lights on protective eyewear, hardhat, etc.) would facilitate hazard recognition.

Develop an inexpensive hand-held earplug test device based on the NIOSH QuickFit concept. Studies of hearing protector users have shown repeatedly that average protection values are much

lower than the labeled Noise Reduction Ratings (NRR) determined in laboratories. A QuickFit test system would help workers determine if their hearing protection is giving them at least 15 decibels of attenuation.

Develop innovative engineering control approaches and technologies for reducing asphalt exposures in roofing, and skin exposures and disease in construction workers.

Conduct research to understand PPE integration and interoperability issues. In most cases, individual PPE are currently used without consideration for their ability to function together. Research is needed to test interfaces among different PPE and components. Current interfaces do not provide seamless integration of PPE components resulting in reduced comfort, fit, usability, and protection for the wearer as well as logistical challenges for safety managers and employers.

Develop innovative educational and professional training materials suitable for today's diverse workplace on the role of PPE in occupational safety and health. This is especially critical for high-risk occupations. Innovative methodologies, including social media, should be explored and evaluated to demonstrate their effectiveness at improving workplace safety and health. For example, to what extent can mobile application media be focused on worker safety and health to provide up-to-date PPE information to a diverse range of employers and employees through portable communication devices?

Conduct research on the ability of existing containment and control strategies to prevent releases and potential human exposures to engineered nanomaterials.

***Impact and Commercialization Potential:*** The impact of the proposed research will prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective equipment. Potential products include technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard.

## **(2) Exposure Assessment Methods for High-Risk Occupations**

***Background:*** Exposure assessment provides multi-disciplinary strategies and methods to anticipate, recognize, evaluate, control, and confirm effective management of occupational health stressors, exposures to those stressors, and resulting health risks. Major gaps in current approaches include: (1) the lack of practical methods for hazard identification and measurement that can be applied at reasonable cost in many workplaces where health stressors may exist, (2) the lack of validated, noninvasive biological methods for monitoring relevant exposure and resulting dose, and (3) the lack of strategies and methods for epidemiologic studies to demonstrate either a dose-response effect or a conclusion of no association between the agent and disease in the complex environments of today's workplaces.

For additional information about NIOSH Exposure Assessment programs, please visit their web site at: <https://www.cdc.gov/niosh/programs/exap/default.html>.

### ***Examples of specific research areas of interest include, but are not limited to:***

Two areas of research are needed to support effective assessment of worker exposure to engineered nanomaterials. 1) Real-time sensors capable of reliably detecting nanoparticles and providing information on size distribution and count, that can be used for personal monitoring; and 2) Development of methods that can detect and quantify the presence of engineered nanomaterials in samples collected for the purpose of characterizing exposures. These methods need to be cost-effective and available to the OS&H practitioner community. Broader application to general public

health assessments should be factored into the research.

Develop new or improved methods to measure occupational health stressors such as psychological and ergonomic factors, noise, chemicals, particles and fibers, physical agents, non-ionizing radiation, or mixtures of stressors in the work environment. Enhanced measurement performance and functionality can include sensitivity, selectivity, size and weight considerations, ease of use, and capabilities to measure multiple analyses simultaneously.

Develop or adapt easy-to-use, direct-reading instruments and test kits to rapidly and inexpensively measure exposures in a variety of workplaces. Critical applications include routine monitoring, evaluating the success of control technologies, and supporting epidemiological studies.

Develop innovative bioaerosol samplers for collecting airborne infectious viruses onto a medium without compromising viability or infectivity to allow exposure assessments in occupational settings.

Improve the measurement of low concentrations of chemicals and biomarkers in biological specimens such as blood, urine, saliva, and sweat so that such concentrations can be linked to internal dose at the intended organs, work tasks and workers can be categorized according to hazard bands and exposure bands, and at-risk workers can be identified and protected.

Develop methods to assess mixed exposures such as chemical mixtures containing gas and particulate matter. Develop improved understanding of dermal exposure's contribution to exposure assessment.

Develop and apply emerging technologies including Artificial Intelligence (AI) models that support and enhance exposure assessment data collection and analysis, particularly involving 'smart' exposure sensors, that could inform control measures.

Develop a computerized system that can be used to predict worker noise exposure from mining machine noise emissions. The system would include an acoustic model of mining environments and algorithms to characterize exposure based on noise source characteristics. The main application for this technology would be for mining machine manufacturers to evaluate the potential effects of noise controls during the design process. If the impact of design changes on exposure reduction can be accurately predicted without the need for extensive field measurements, innovative noise controls can reach implementation much more quickly.

***Impact and Commercialization Potential:*** This research will lead to the development of practical solutions and prevention activities to address complex problems that cause occupational diseases, injuries, and fatalities and that will lead to reductions in occupational injuries and illnesses among all workers. This research will lead to the development and translation of exposure assessment methods and research findings into prevention practices and products that will be adopted in occupational settings. Potential products include technical methods, processes, techniques, tools, and materials that support the assessment of exposure to physical, chemical, and biological hazards in the work environment.

### **(3) Work-related Injuries from Motor Vehicle Crashes**

***Background:*** The risk of injury associated with on-the-job operation of motor vehicles affects millions of U.S. workers who work in all industries and drive all types of vehicles, and for whom driving may be a primary or incidental job task. Motor vehicle crashes are consistently the leading cause of work-related fatalities in the United States. From 2011 through 2022, the Bureau of Labor Statistics reported 21,046 work-related fatalities due to motor vehicle crashes, about 35% of all fatalities at work. Over the same period, workers incurred nearly 515,000 lost-workday injuries due to these crashes. Crash-related fatalities and serious injuries have a devastating impact on workers and their families, and on the economic health and productivity of American businesses. Work vehicles such as large trucks also have an impact on the safety of the motoring public.

The [NIOSH Center for Motor Vehicle Safety](#) coordinates the CDC/NIOSH response to this pressing worker safety issue. Many NIOSH programs include motor vehicle crashes among their top injury prevention priorities: Traumatic Injury; Transportation, Warehousing, and Utilities; Wholesale and Retail Trade; Oil and Gas Extraction; and Public Safety.

**Examples of specific research areas of interest include, but are not limited to:**

The highest priority is to develop, implement, and evaluate interventions in an effort to build the scientific evidence base to prevent work-related motor vehicle crashes and resulting injuries. This may be achieved by:

Developing and testing new design concepts and applications with potential for commercialization and diffusion to employers and fleet managers.

Developing and testing novel approaches for driver training and assessment to reduce work-related motor vehicle crashes, including training on the operation of vehicles with Advanced Driver Assistance Systems (ADAS) or other forms of automation.

Developing and evaluating the effectiveness of technology- or management-based intervention strategies to reduce the incidence or severity of work-related motor vehicle crashes.

Developing and evaluating engineering controls for preventing work-related crashes and injuries, with emphasis on specialized work vehicles such as large trucks and fire apparatus.

Developing or evaluating an intervention designed to prevent crashes and injuries for a disproportionately affected group, such as roadside assistance workers or pedestrian workers engaged in construction or maintenance of roadways.

Developing and evaluating an easy-to-use computerized system based on readily available technology that can automate a “fatigue detection” system capable of warning the employee driver and supervisor when the driver may be at risk for a work-related motor vehicle crash. The system would include a statistical algorithm capable of using Global Positioning System (GPS) data from cellular phones to characterize potential number of hours awake within the last 24 hour-cycle. The main application for this technology would be to allow supervisors and employee drivers to identify and respond to fatigue, thereby reducing the driver’s risk of a fatigue-related crash.

Developing and evaluating technologies to reduce crash and crash-related injury risk among gig workers who deliver packages, takeout food, and groceries, whose jobs are linked to a digital online platform.

***Impact and Commercialization Potential:*** Application of evidence-based interventions is expected to have a large impact on reducing the incidence and severity of work-related motor vehicle crashes. This will yield substantial public health benefits and will positively affect workers’ compensation and health insurance premiums and costs. CDC/NIOSH has well-established working relationships with employers, their trade associations, and standards-setting organizations, and is therefore strongly positioned to communicate findings and guidance to potential users. CDC/NIOSH also has strong infrastructure to facilitate the transfer of technology-based interventions to the marketplace. Given the extremely short induction period between exposure and injury occurrence, CDC can make a measurable difference in a very short period (< 4 years).

Visit the NIOSH homepage for more information on NIOSH’s research program areas <http://www.cdc.gov/niosh/homepage.html>.

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## FOOD AND DRUG ADMINISTRATION (FDA)

### Mission

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information they need to use medicines and foods to improve their health.

For additional information about areas of interest to the FDA, please visit our home page at <http://www.fda.gov>.

### Budget Guidance

FDA will not fund:

- Phase I applications greater than \$200,000
- Phase II applications greater than \$1,500,000

### Specific SBIR and STTR Program Information

FDA will not accept SBIR applications that propose clinical trials, and all of the topics listed below must be for projects that do not propose clinical trials.

### Clinical Trials

Does FDA accept Clinical Trials through the Omnibus/Parent Notices of Funding Opportunities?	No	
Does FDA accept Clinical Trials through specific Notices of Funding Opportunities?	No	
Does FDA support Clinical Trials through NON-SBIR/STTR Notices of Funding Opportunities?	No	

## CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

### Mission

CBER is responsible for ensuring the safety, efficacy, potency and purity of biological and related products intended for use in the treatment, prevention or cure of diseases in humans as well as the safety of the nation's supply of blood and blood products. The primary responsibility of CBER is to review the

quality, safety and efficacy of vaccines, blood products, certain diagnostic products and other biological and biotechnology-derived human products.

CBER's activities include: evaluating the quality, safety and effectiveness of biological products before marketing, and monitoring the pre-clinical and clinical testing of new biological products; licensing biological products and manufacturing establishments, including plasmapheresis centers, blood banks, vaccine and biotechnology manufacturers; AIDS program and policy activities, including research on AIDS therapeutic products, diagnostic tests and vaccines; research to establish product standards, develop improved testing methods and assess the safety of biological products; compliance, lot release program and post market surveillance; meeting PDUFA goals, new research programs, and new regulatory initiatives (managed review process for all products).

## **CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

### **Mission**

CDER develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use; evaluates new drug applications and investigational new drug applications; develops standards for the safety and effectiveness of all over-the-counter drugs; monitors the quality of marketed drugs through product testing (bioavailability/bioequivalence testing), post marketing surveillance, and compliance programs; develops guidelines on good manufacturing practices; conducts research and develops scientific standards on composition, quality, safety, and efficacy of human drugs.

Drug regulatory research as conducted in CDER is directed at the discovery of new knowledge relevant to drug development, post marketing drug experience (patterns of drug use and safety), and drug regulation to enhance FDA regulatory decisions. These drug regulatory decisions impact on the development of regulations, guidelines and guidance for the regulated industry and provide clarity and consistency in application of CDER regulatory requirements. These drug regulatory decisions also impact public health by ensuring that marketing drugs are safe and efficacious and that their risk: benefit profile remains acceptable during the market life of a drug. Specific areas of research conducted by the Center include Pharmacology/toxicology, microbiology/virology, clinical pharmacology, pediatric issues in drug therapy, post marketing drug safety, evaluation of effectiveness of regulatory actions, patterns of drug use, including off-label, signal detection methodologies (e.g., data mining techniques), epidemiologic studies of therapeutics using population-based data, regulatory compliance, product quality, and active surveillance methods.

### **Research Topics**

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Develop a system for gathering real-time data on physician prescribing behavior, understanding and compliance with drug product labeling and frequency of off-label prescribing.
- B. Develop and evaluate the effectiveness of new methods and tools for managing the known risks of marketed drug products (e.g., communicating newly identified risks to health care practitioners and patients).
- C. Develop methods for timely active surveillance of newly approved drug products in large populations to identify both expected and unexpected outcomes.

- D. Develop methods for actively collecting information on all cases of classically drug-associated events (e.g., acute liver failure, blood dyscrasias, severe desquamating skin disorders) to augment the FDA's current passive surveillance system.
- E. Develop improved clinical markers and methods with potential for bed-side application for detection of the early onset of adverse drug events.
- F. Develop surrogate potency methods for biotech drug products to replace traditional animal testing.
- G. Development of psychochemical and in-vitro biological tests to evaluate pharmaceutical equivalence of complex drug substances and drug products.
- H. Research into approaches to handle informative missing patient data in clinical trials, including innovations in study designs and statistical methods of analysis.
- I. Statistical and computational methods and strategies for the design, analysis and interpretation of microarray, genomic and proteomic data.

## **CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)**

### **Mission**

The FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for the meat, poultry, and processed egg products that are regulated by the USDA. Consequently, CFSAN seeks research designed to complement and accelerate efforts aimed at the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, colors, and cosmetics. CFSAN conducts research, and develops regulations, guidance and standards related to the composition, quality, nutrition, and safety of food, food additives, colors, and cosmetics. The Center evaluates FDA's surveillance and compliance programs relating to foods, colors, and cosmetics; reviews industry petitions, and develops regulations for food standards to permit the safe use of color and food additives.

### **Research Topics**

CFSAN maintains an active research program that is focused on the following priorities; ensuring the safety of food, dietary supplements and cosmetics; improving nutrition; and promoting the security and integrity of the food supply. The Center's research activities are intended to; support the FDA's regulatory activities; reduce the incidence of foodborne illness by improving our ability to detect and quantify foodborne pathogens, toxins, and chemicals that could jeopardize the safety and security of the food supply; find new and improved ways to control these agents; and safely produce, process, and handle food and food products. FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible while at the same time protecting the nation's food supply. Mission-critical knowledge gaps are addressed through translation research focused on the risks associated with FDA regulated products throughout their life cycles, from production to consumption. Ideally extramural research is sought that complements the Center's intramural research efforts, and which will enhance the Agency's and the Nation's ability to reduce the incidence of foodborne illness and protect the integrity of the nation's food supply. FDA's mission-critical needs require that the research not simply end with the generation of new knowledge and technologies but extend to the validation of new approaches by using realistic conditions that accurately reflect the diversity of the food industry and offer potential solutions that can be accepted by appropriate sectors of the food industry.

## **CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)**

### **Mission**

CDRH is responsible for assuring patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. Towards this goal, CDRH develops policy, conducts regulatory science, and evaluates the safety and effectiveness of medical devices and radiation-emitting products. CDRH classifies medical devices into one of three classes based on risk and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. CDRH reviews study protocols for investigational devices, applications for authorization of medical devices, and evaluates exemption requests for investigational devices. CDRH is integrally involved in developing national and international standards, establishing good manufacturing practices, and driving postmarket surveillance and compliance programs. The radiation safety programs at CDRH involve enforcement of mandatory requirements in addition to partnerships and voluntary programs that promote the safe use of radiation-emitting products. The Center develops and conducts research and testing programs in the areas of physical, life, and engineering sciences related to the human health effects of radiation and medical device technologies, provides expertise and analyses for health-risk assessments, and also develops new or improved measurement methods, techniques, instruments and analytical procedures for evaluating product performance and reliability.

### **Research Topics**

CDRH welcomes submissions that aid in assessment of safety, effectiveness, and performance of medical devices and/or promote medical device innovation. Please note, we do not fund development of any products that may eventually be regulated by the Center. Areas of interest and examples are listed below.

- A. **Biocompatibility and Alternative Methods:** Develop and advance reliable alternatives to traditional in vivo biocompatibility testing approaches to characterize biological response to extracts of medical devices and particulates, including
  - novel in vitro, ex vivo, and in silico models, microphysiological systems, alternative assays
  - frameworks capable of leveraging clinical, animal, and material information not obtained through biocompatibility testing to be used as a substitute or to justify performing more focused safety analyses
  - tools for assessing toxicological risk and chemical characterization in cases where traditional extraction methods are not feasible and/or reference standards do not exist.
- B. **Digital Health and Cybersecurity:** Enhance the performance of digital health technologies and promote medical device cybersecurity, including digital health technologies that facilitate remote clinical trials and AI/ML algorithm evaluation methodologies.
- C. **Electrical and electromagnetic compatibility safety evaluation methods for non-clinical environment use** taking into consideration common EM emitters such as radiofrequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), and Cellular 5G.

- D. Health Equity: Advance the development of knowledge, and safe and effective technologies, to meet the needs of diverse patient populations and consumers, including reducing barriers to participate in evidence generation by diverse populations and the use of medical technologies outside a healthcare setting.
- Health of Women: Explore unique issues related to the performance of medical devices in women, improve analysis and communication of sex- and gender- specific data to better assure the safe and effective use of medical devices
  - Human Factors: Explore methodologies to test and report on usability or user experiences with devices in diverse patient populations and consumers.
  - Pediatric Medical Device Development: Increase and accelerate medical device development and labelling for the unique and evolving needs of pediatric and special populations, especially younger sub- populations such as neonates and children. Optimize or develop infrastructure that supports safe innovation and development of medical devices designed, evaluated, and labelled for pediatric and special populations.
- E. Sterilization: Encourage the development of new approaches to medical device sterilization with a focus on identifying alternatives to ethylene oxide (EtO) sterilization methods, and/or development of strategies to reduce EtO emissions.

## **CENTER FOR VETERINARY MEDICINE (CVM)**

### **Mission**

CVM protects human and animal health by ensuring the safety and effectiveness of animal drugs, by ensuring the safety of animal food (and food ingredients), and by addressing safety concerns that may arise with the use of animal devices. The Center makes timely, quality decisions and takes regulatory actions to ensure that these products are protective of public health, provide for quality health care of animals, minimize the transmission of diseases, and increase the efficiency of production of animal- derived food and fiber. The Center, in partnership with Federal and state agencies and others, ensures animal health and the safety of food derived from animals. Regulatory decisions are supported by research, the monitoring of product safety, and efficacy, and continuous process improvement.

### **Research Topics**

Research and development opportunities within the Center for Veterinary Medicine that lend themselves to performance by small businesses include, but are not limited to, the following areas of interest:

- A. Development, for the specific purpose of obtaining approval or conditional approval, of products for the treatment, control or prevention of diseases or conditions for which limited approved therapeutic options are available, particularly those occurring in minor species or small numbers of major species.
- B. Development and validation of high throughput/screening of quantitative and qualitative analytical methods for analyzing drugs, additives, and contaminants (chemical and microbial) in animal tissues and feeds.

- C. Development of methods and approaches to determine absorption, distribution, metabolism, and excretion of drugs, food additives and contaminants (microbial and chemical) in animals, including minor species. This includes, among other topics, 1) the development of alternative methods, in support of replacement/reduction/refinement for activities involving animal research, and 2) methods for the determination/validation of bioequivalence.
- D. Development of new biomarkers and models for determining the safety and effectiveness of veterinary drugs and food additives in animals, including minor species or development of alternative methods to animal use.
- E. Development of methods to determine the effects of drugs, food additives, and contaminants (microbial and chemical) on immunological and physiological functions of animals, including minor species.
- F. Development/refinement of One Health approaches to monitor and minimize antimicrobial resistance development and to support antimicrobial stewardship in animals.
- G. Development of methodology for accelerated (short term) shelf-life stability testing for drugs and food additives for extrapolation to real time stability testing.

## **OFFICE OF CRITICAL PATH PROGRAMS**

### **Mission**

The Office of Critical Path Programs, in FDA's Office of the Chief Scientist, coordinates the cross-agency Critical Path Initiative (CPI), FDA's strategy for transforming the way medical products are developed, evaluated, and manufactured. CPI activities are under way throughout the Agency, from the product centers to the Office of the Commissioner. For details, see <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>. Collaboration is key to the CPI initiative because bringing safe, effective, and innovative therapies to the American public requires FDA to leverage the resources and expertise of all stakeholders, including other Federal agencies, academia, healthcare professionals, patient and consumer groups, regulated industry, and health-related organizations. In 2008, CPI collaborations involved 84 government agencies, universities, industry leaders, and patient groups from 28 states and 5 countries on a raft of groundbreaking research projects.

### **Research Topics**

Research and development opportunities within FDA that lend themselves to performance by grantees include, but are not limited to, the following:

- A. Studying the immunological correlates of TB immunity and developing tools to evaluate TB vaccine efficacy.
- B. Developing study models for testing combination-antimicrobials as a strategy to prevent the development of drug resistance.
- C. Developing new approaches to preclinical safety testing.
- D. Identifying biomarkers for safety and efficacy evaluation of medical products.

## OFFICE OF ORPHAN PRODUCTS DEVELOPMENT

### Mission

The Office of Orphan Products Development was established to identify and facilitate the development of orphan products. Orphan products are drugs, biologics, medical devices and foods for medical purposes, which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States). These products may be useful in a rare disease/disorder but lack commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products in which there is evidence suggesting usefulness in a rare disease/disorder but which are not labeled for that disease/disorder because substantial evidence of safety and effectiveness for that use is lacking.

### Research Topics

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Development of products for the treatment of rare diseases or disorders including but not limited to neurological, metabolic, genetic, ophthalmologic, hematologic, and dermatological diseases or disorders for the specific purpose of obtaining marketing licensure.
- B. Development of products for use in diagnosis of rare diseases for which the diagnostic tool would be used in fewer than 200,000 persons annually in the United States.
- C. Development of vaccines for the prevention of rare diseases to be used in fewer than 200,000 persons annually in the United States.

For additional information on research topics and administrative and business information, contact

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