NIH NATIONAL CANCER INSTITUTE

# THE GRANTS PROCESS

## The Lifecycle of a Grant

U.S. Department of Health & Human Services | National Institutes of Health

# THE NATIONAL CANCER INSTITUTE: BUILDING ON OPPORTUNITIES IN CANCER RESEARCH

# PREFACE

The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH), which is one of 11 agencies that compose the Department of Health and Human Services (HHS). The NCI, established under the National Cancer Institute Act of 1937, is the Federal Government's principal agency for cancer research and training.

The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program. The National Cancer Institute coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients. The NCI 's support of the National Cancer Program is multi-faceted; however, a significant aspect is to provide research grants and cooperative agreements to coordinate and support research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad.

The purpose of this publication is to provide a broad overview and general description of the grant process as it relates to the National Cancer Institute (NCI). We hope that this information will provide a starting point to understanding the overall process but encourage readers to seek detailed information at the NCI website, www.cancer.gov and through additional resources provided at the end of the publication.

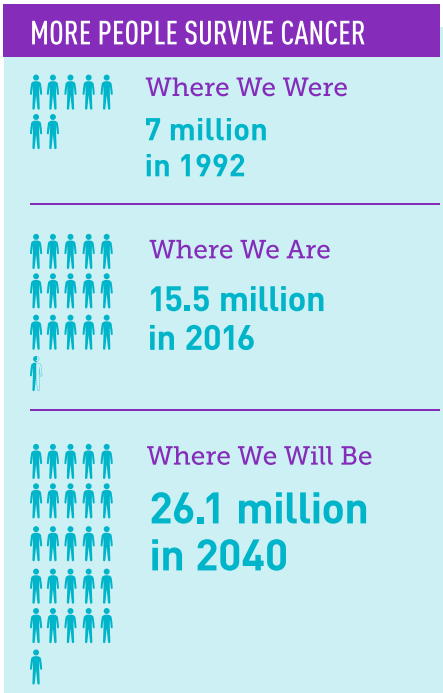
It is a pleasure to acknowledge the staff of the NCI and the NIH whose contributions make this publication possible. For additional information concerning the subject matter in the publication, the NCI Office of Grants Administration is pleased to answer any inquiries. This publication along with other general information regarding the Office of Grants Administration can be found at: http://www.cancer.gov/about-nci/organization/oga.

Thank you,

**Crystal Wolfrey**

**Chief Grants Management Officer**

**Director, Office of Grants Administration**



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The organization of this publication represents a progression of the NCI grants process and administration including the following information.


# NCI OVERVIEW: A RICH HISTORY & MISSION

The National Cancer Institute (NCI) was founded by Congress in The National Cancer Act of 1937. It was the first institute founded as part of what would later become the National Institutes of Health (NIH) comprised of 27 Institutes and Centers, an Operating Division of the Department of Health and Human Services (HHS). The NCI is headquartered on the NIH campus in Bethesda, MD, with satellite offices in Rockville and Frederick, MD.

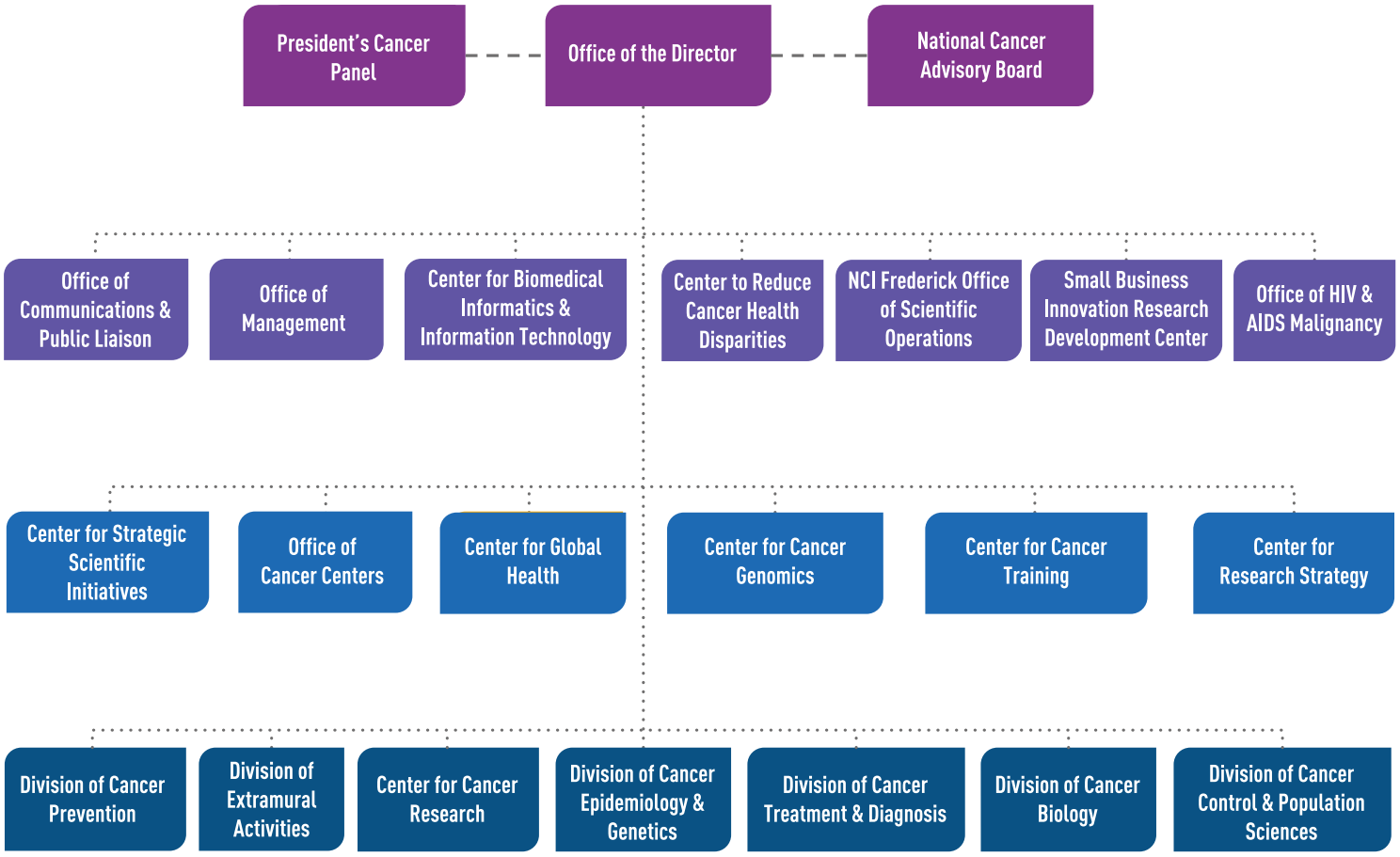
## The Department of Health and Human Services (HHS)

HHS is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. There are 11 Operating Divisions within the HHS including the National Institutes of Health.

## The National Institutes of Health (NIH)

As an operating division of the HHS, NIH is the nation's medical research agency – supporting scientific studies that turn discovery into health. NIH is the largest source of funding for medical research in the world creating hundreds of thousands of high-quality jobs by funding thousands of scientists in universities and research institutions in every state across America and around the globe. NIH is made up of 27 Institutes and Centers, each with specific research agendas. For over a century, NIH scientists have paved the way for important discoveries that improve health and save lives. In fact, 156 Nobel Prize winners have received support from NIH including recent National Cancer Institute Director, Dr. Harold Varmus.

Figure 1: Office of the Director, NCI



## The National Cancer Institute (NCI)

### WHAT ARE THE NCI'S MAIN RESPONSIBILITIES AND ACTIVITIES?

NCI's initial responsibilities, as defined in the National Cancer Act, included the following:

- Conducting and fostering cancer research
- Reviewing and approving grant-in-aid applications to support promising research projects on the causes, diagnosis, treatment, and prevention of cancer
- Collecting, analyzing, and disseminating the results of cancer research conducted in the United States and in other countries
- Providing training and instruction in cancer diagnosis and treatment

NCI's responsibilities were later expanded and strengthened in the National Cancer Act of 1971. In this legislation, Congress created the National Cancer Program and charged NCI with its coordination.

The National Cancer Act of 1971 also expanded the scope of NCI's international activities to include support of cancer research outside the United States by highly qualified foreign nationals, collaborative research involving U.S. and foreign participants, and training of U.S. scientists abroad and foreign scientists in the United States.

Additional legislation, the current Public Health Service Act, also charged NCI with continuing and expanding programs to provide physicians and the public with state-of-the-art information about the treatment of individual types of cancer and to identify clinical trials that might benefit patients while advancing knowledge of cancer treatment. The Act also expanded NCI's dissemination activities to include providing information and education programs for patients and the public to help individuals take steps to do the following:

- Reduce their risk of cancer
- Make them aware of early detection techniques and motivate the appropriate utilization of these techniques
- Help individuals deal with cancer if it strikes
- Provide information to improve long-term survival

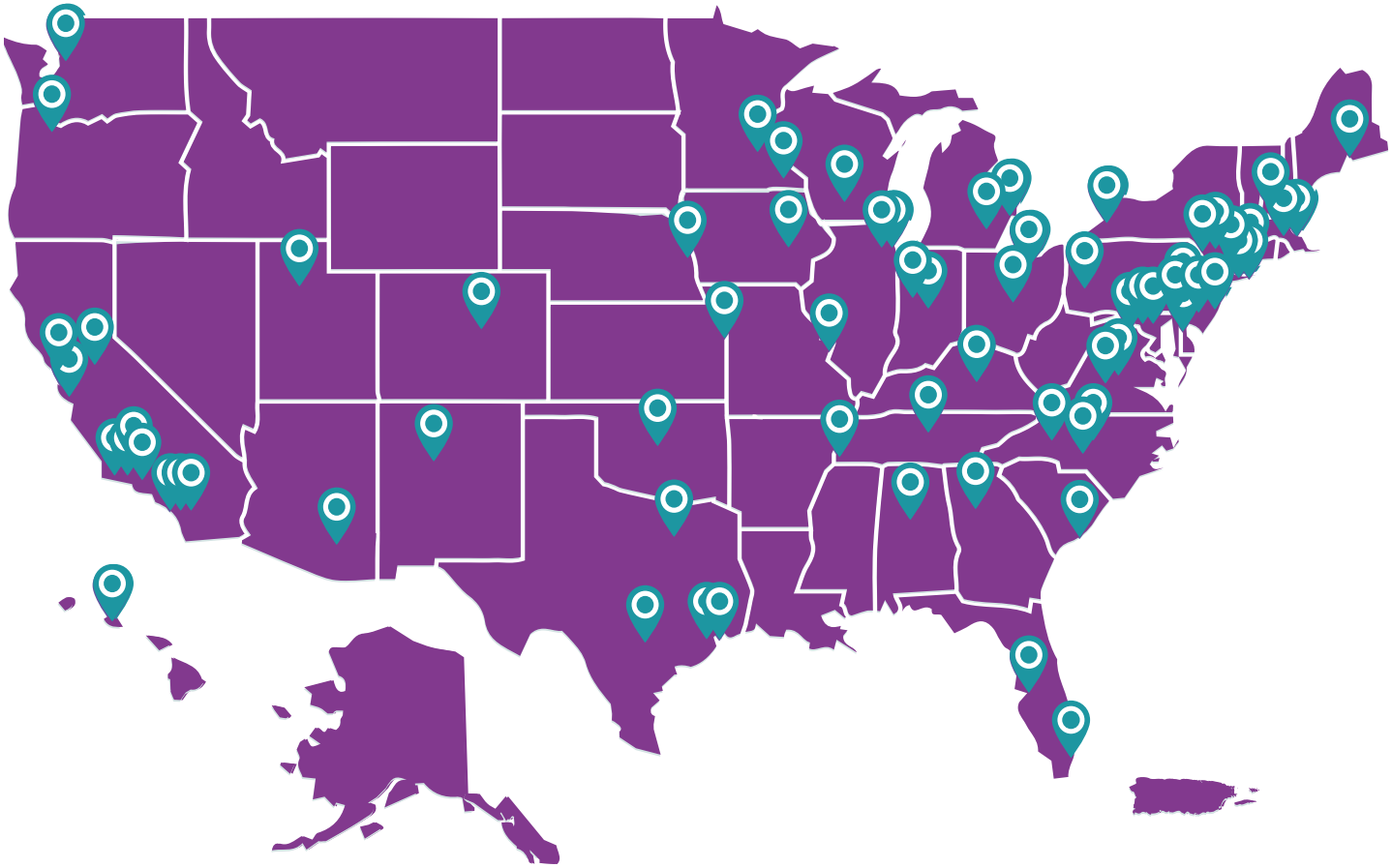
### HOW HAS NCI FULFILLED ITS RESPONSIBILITIES?

NCI has built a national network of regional and community cancer

centers, physicians who are cancer specialists, cooperative groups of clinical researchers, and volunteer and community outreach groups.

Figure 2: NCI-Designated Cancer Centers

The 71 NCI-Designated Cancer Centers are at the forefront of NCI-supported efforts at universities and cancer research centers across the United States. The centers are developing and translating scientific knowledge from promising laboratory discoveries into new treatments for cancer patients. There are 13 cancer centers, 51 comprehensive cancer centers, and 7 basic laboratory cancer centers.



cancer.gov/cancer-centers

In addition, it has developed an infrastructure for discovery that consists of support mechanisms, organizations, and networks that link scientists, facilities, resources, and information. This infrastructure provides the foundation for basic, translational, and clinical research activities encompassing all aspects of cancer, including the following:

- Biology
- Genomics
- Causes
- Childhood Cancer
- Clinical Trials
- Diagnosis
- Prevention
- Screening & Early Detection
- Treatment
- Public Health
- Global Health
- Cancer Health Disparities

NCI's infrastructure also supports training programs to ensure the continuous development of highly skilled researchers in basic, clinical, cancer control, behavioral, and population sciences.

Each year, the efforts of thousands of researchers supported by this infrastructure produce scientific advances in all areas of cancer research. Furthermore, NCI has initiated cancer control programs to hasten the application of knowledge gained through research.

## ARE WE MAKING PROGRESS AGAINST CANCER?

Because of the work of NCI scientists and cancer researchers throughout the United States and the rest of the world, real progress is being made against cancer. The most recent Annual Report to the Nation on the Status of Cancer[1] was released in 2019.

According to the report:

Overall cancer death rates continue to decrease in men, women and children for all major racial and ethnic groups.

Overall cancer incidence rates, or rates of new cancers, have decreased in men and remained stable in women.

1. *Cancer Trends Progress Report National Cancer Institute, NIH, DHHS, Bethesda, MD, February 2019, https://progressreport.cancer.gov. Annual Report to the Nation on the Status of Cancer, Journal of the National Cancer Institute, NIH, DHHS, Bethesda, MD, May 30, 2019.*
www.cancer.gov/research/progress/annual-report-nation

## NCI MISSION

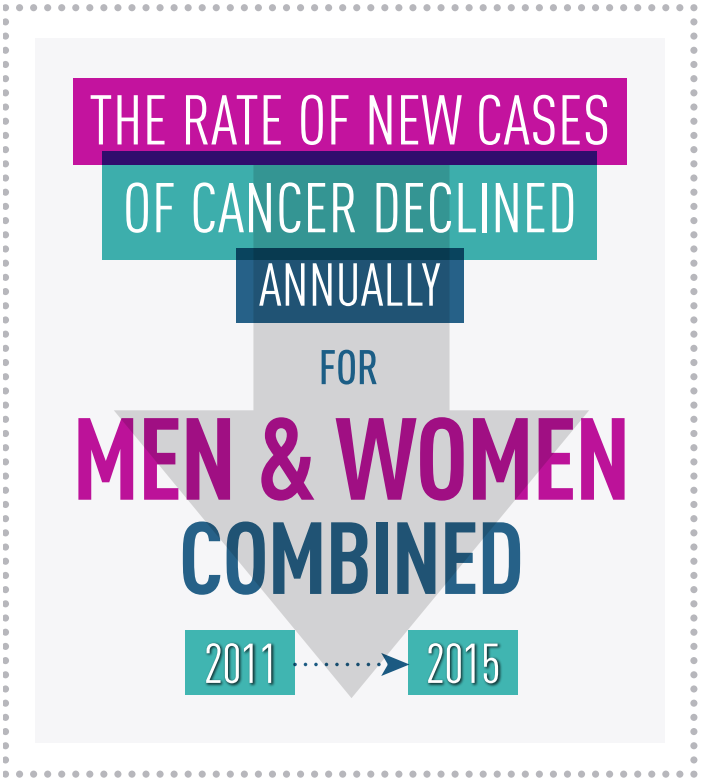
The NCI is the federal government's principal agency for cancer research and training. The NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and their families. Specifically, the Institute: Supports and coordinates research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad through research grants and cooperative agreements.

- Conducts research in its own laboratories and clinics.
- Supports education and training in fundamental sciences and clinical disciplines for participation in basic and clinical research programs and treatment programs relating to cancer through career awards, training grants, and fellowships.
- Supports research projects in cancer control.
- Supports a national network of cancer centers.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.
- Encourages and coordinates cancer research by industrial concerns where such concerns evidence a particular capability for programmatic research.
- Collects and disseminates information on cancer.
- Supports construction of laboratories, clinics, and related facilities necessary for cancer research through the award of construction grants.

## ORGANIZATION

The NCI's Office of the Director serves as the focal point for the National Cancer Program, with advice from the President's Cancer Panel, the National Cancer Advisory Board (NCAB), the Board of Scientific Counselors (BSC), and the Board of Scientific Advisors (BSA).

Figure 3: Rate of New Cancer Cases

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One intramural research Center (Center for Cancer Research), one intramural research Division (Division of Cancer Epidemiology and Genetics), and five extramural research Divisions monitor and administer the NCI's cancer research activities through extramural and intramural research programs.

The Office of the Director coordinates initiatives across the NCI's five extramural research divisions:

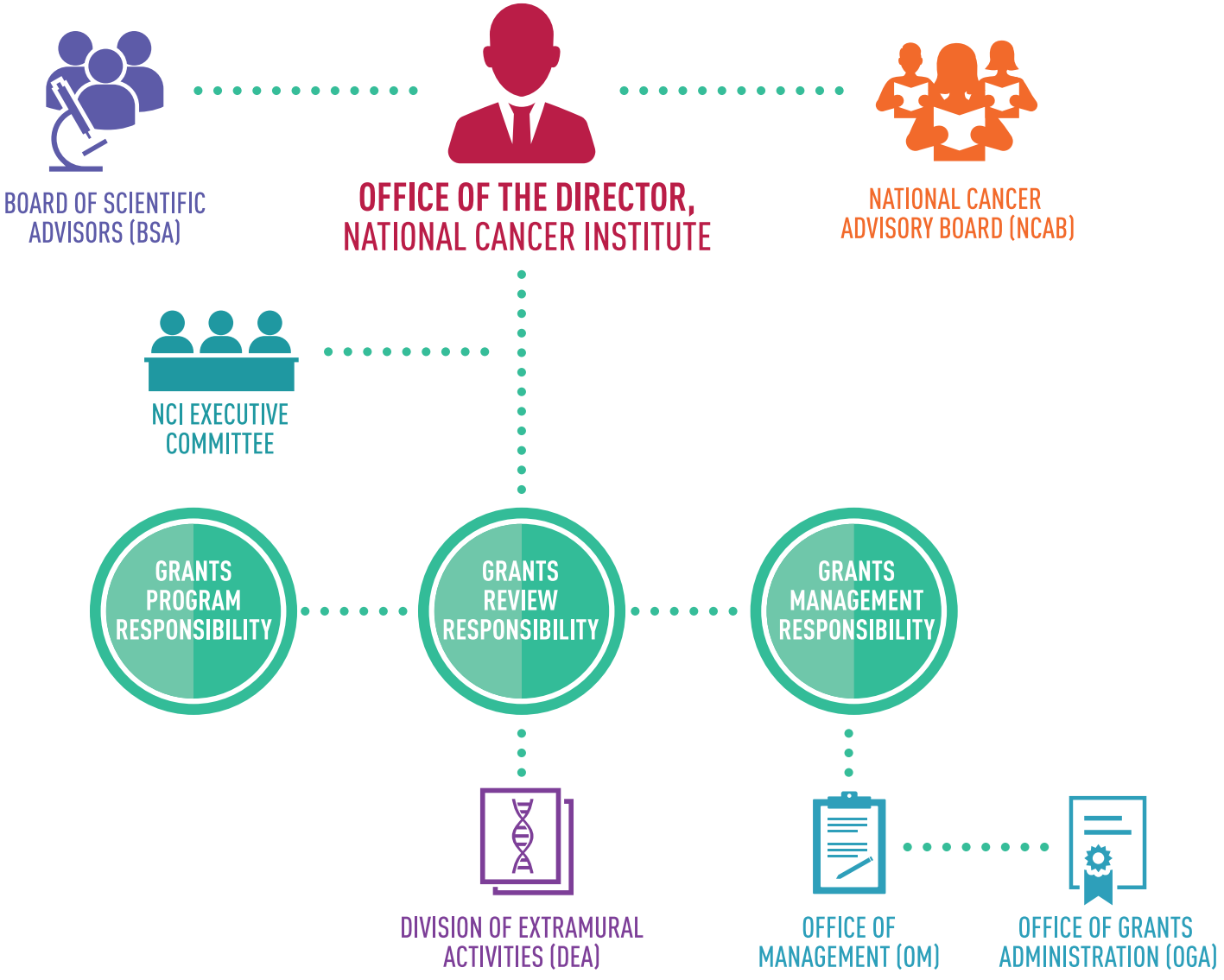
- Division of Cancer Biology (DCB) – Encourages and facilitates continued support of basic research in all areas of cancer biology to provide the research foundation which enables improved understanding of the disease and may lead to new approaches for prevention, diagnosis, and treatment.
- Division of Cancer Control and Population Sciences (DCCPS) – Conducts and supports an integrated program of genetic, epidemiological, behavioral, social, applied, and surveillance cancer research to reduce risk, incidence, and deaths from cancer as well as enhance the quality of life for cancer survivors.
- Division of Cancer Prevention (DCP) – Conducts and supports research to find ways to prevent and detect cancer, and to prevent or relieve symptoms from cancer and its treatments.
- Division of Cancer Treatment and Diagnosis (DCTD) – Supports the translation of promising research into clinical applications to improve the diagnosis and treatment of cancer in areas of unmet need that are often too risky or difficult for industry or academia to develop alone.
- Division of Extramural Activities (DEA) – Coordinates the scientific review of extramural research before funding and provides systematic surveillance of that research after awards are made to assist the NCI in achieving its goal of a balanced research portfolio. The DEA manages the functions of the NCAB and the BSA.

## EXECUTIVE COMMITTEE

The NCI Executive Committee (EC), which consists of high-level Institute managers, makes all major organizational and operating decisions affecting the NCI, including:

- Formulating scientific and management policy decisions
- Establishing funding plans for grant programs not administered solely by one Division

Figure 4: Extramural Grants Program



- Approving certain exceptions to grant funding plans
- Reviewing contract, cooperative agreement and grant concepts
- Formulating the long-range strategic plan for the Institute
- Addressing trans-NCI policy issues affecting personnel and resources

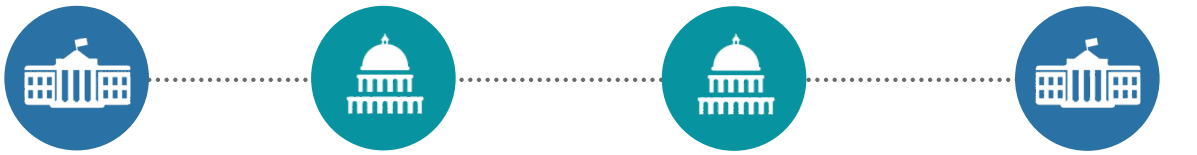
## BUDGET DEVELOPMENT

The budget development cycle for a fiscal year is about 30 months, with three phases – formulation, presentation, and execution – overlapping. For example, the current fiscal year approved budget is being executed while the next upcoming fiscal year is being presented for consideration and the subsequent year is in the process of being formulated.

In the National Cancer Act of 1971, NCI was given the authority to prepare and submit an annual budget proposal directly to the President for review and transmittal to Congress. This authority is unique to NCI, and the budget proposal created in response to it is often referred to as the "NCI Professional Judgment Budget." In January, the President's budget is submitted, and congressional justification hearings are held in February, March, or April. Final appropriation amounts must be approved by both the House of Representatives and the Senate and signed by the President to be enacted into law.

### Figure 5: How NCI Receives Its Funding

NCI receives its funding, or appropriation, from Congress as part of the overall federal budget process.



**STEP 1**

OMB coordinates with federal agencies to formulate the President's Budget, which covers all federal agencies (including NCI and NIH) and reflects the President's priorities. The President submits the budget to Congress, which must pass appropriations legislation that funds federal agencies.

**STEP 2**

The Congressional appropriations committees consider the President's Budget as they prepare appropriations legislation for the next fiscal year.

**STEP 3**

The appropriations committees finalize their legislative proposals, and the House and Senate consider the proposed legislation. Once passed and reconciled into a unified bill, Congress sends the legislation to the President.

**STEP 4**

The President signs the appropriations bill into law, making funds available to executive agencies, including NCI and NIH.

**NCI Professional Judgment Authority**

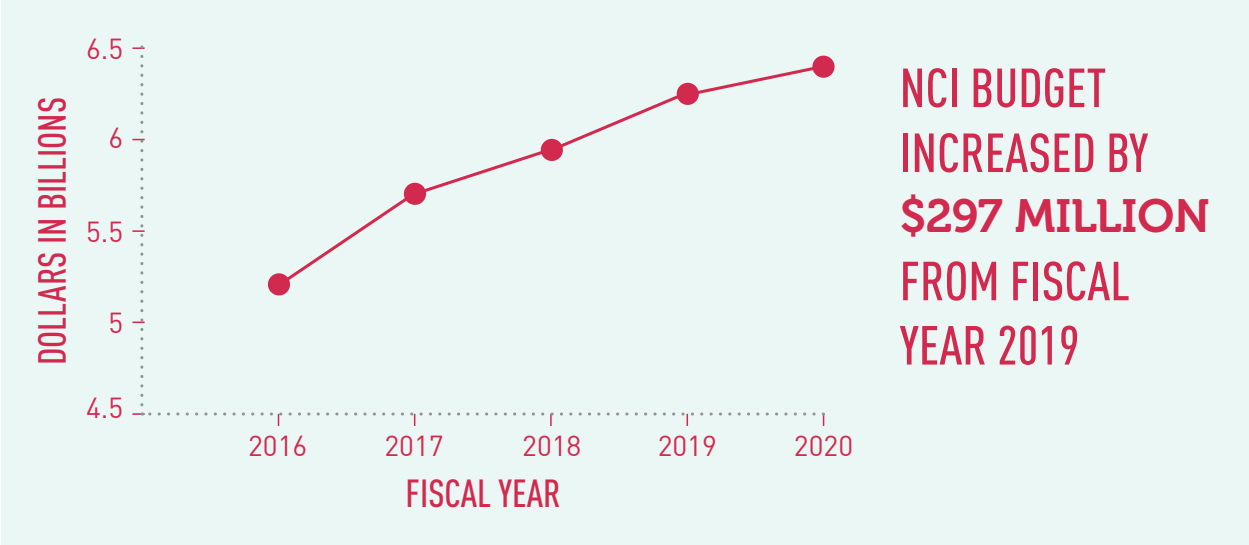
The National Cancer Act of 1971 gives the NCI Director special authority to submit an annual professional judgment budget directly to the President for review and delivery to Congress. This budget reflects NCI cancer research priorities and identifies areas of potential investment in cancer research.

cancer.gov

Source: http://obf.cancer.gov | http://obf.cancer.gov/financial/factbook.htm | http://www.whitehouse.gov/omb

The NCI fiscal year budget has increased for the last three fiscal years. The vast majority of the budget is used to fund grants and contracts to universities, medical schools, support cancer centers, research laboratories, and private companies in the United States and about 60 other countries around the world. The balance of the funds support research activities conducted at NCI.

Figure 6: Current Fiscal Year (FY 2020) Budget

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Source: 2018 NCI Budget Fact Book

## NCI BUDGET ACTIVITIES

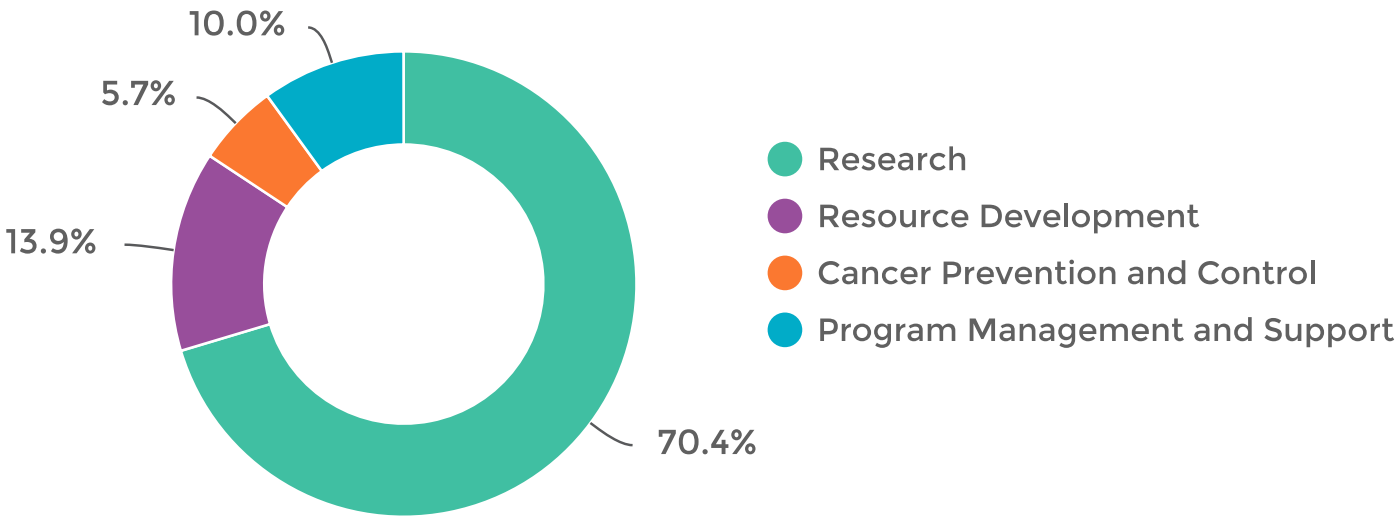
**Research:**

**Cancer Causation** – research concentrates on the events involved in the initiation and promotion of cancer. It encompasses: chemical and physical carcinogenesis, biological carcinogenesis, epidemiology, chemoprevention, nutrition research

**Detection & Diagnosis** – research includes studies designed to: improve diagnostic accuracy, provide better prognostic information to guide therapeutic decisions, monitor response to therapy more effectively, detect cancer at its earliest presentation, identify populations and individuals at increased risk for the development of cancer.

**Treatment** – research is composed of preclinical and clinical research. Preclinical research focuses on the discovery of new antitumor agents

Figure 7: NCI's Program Structure for FY 2018

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and their development in preparation for testing in clinical trials. These agents include both synthetic compounds and natural products. Clinical research involves demonstrating the effectiveness of new anticancer treatments through the systematic testing in clinical trials.

Phase I Trial – The first step in testing a new treatment in humans. These studies test the best way to give a new treatment (for example by mouth, intravenous infusion, or injection) and the best dose. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Since little is known about the possible risks and benefits of the treatments being tested, Phase I trials usually include only a small number of patients who have not been help by other treatments.

Phase II Trial – A study to test whether a new treatment has an anticancer effect (for example, whether is shrinks a tumor or improves blood test results) and whether it works against a certain type of cancer.

Phase III Trial – A study to compare the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group has better survival results or fewer side effects). In most cases, studies move into Phase III only after a treatment seems to work in Phases I and II. Phase III trials may include hundreds of people.

**Cancer Biology** – supports a broad spectrum of research, including

the body's response to cancer. Since cancer is the result of genetic damage that accumulates in stages, it is the goal of cancer biology to identify and explain the stepwise progression between the initiating event in the cell and final tumor development. Studies include: investigations of cellular and molecular characteristics of tumor cells, interactions between cells within a tumor, components of host immune defense mechanisms.

**Resource Development:**

**Cancer Centers Support** – the program consists of a group of individual, nationally recognized, geographically dispersed institutions with outstanding scientific reputations. Each institution reflects particular research talents and special technological capabilities. Cancer Centers have developed in a number of different organizational settings. Some are independent entities dedicated entirely to cancer research (freestanding Centers); some have been formed as clearly identifiable entities within academic institutions and promote interactive cancer research programs across departmental and/or college structures (matrix Centers); and others involve multiple institutions (consortium Centers). Specialized Programs of Research Excellence (SPOREs) are designed to stimulate translational research from the lab to clinical practice. SPOREs focus on prevention, detection, diagnosis, and treatment research for a single cancer site. The NCI's Comprehensive Minority Institution/Cancer Center Partnership awards are cooperative agreements designed to establish comprehensive partnerships between Minority-Serving Institutions and NCI-designated Cancer Centers. The partnerships focus on cancer research and one or more target areas in cancer research training and career development, education, or outreach programs to minority communities.

**Research Manpower Development** – program supports and maintains a pool of trained scientists qualified to perform cancer research. Grants primarily provide support for basic and clinical scientists. The National Research Service Award Program is the major mechanism for providing long-term, stable support for a wide range of promising scientists and clinician. Individual awards are made directly to both pre-and postdoctoral fellows, while institutional awards are made to scientists who, together with a group of faculty preceptors, administer a comprehensive research training program. The program is geared toward support for both scientists and research physicians during the first 3 to 5 years between receipt of a Ph.D., M.D., or other professional degree and receipt of an individual investigator-initiated award.

**Buildings and Facilities**

**Cancer Prevention and Control**

The NCI Cancer Prevention and Control Program conducts basic and applied research through both intramural and extramural mechanisms. A key priority of this program is to develop strategies for the effective translation of knowledge gained from prevention and control research into health promotion and disease prevention activities for the benefit of the public. There are four components of the program: Cancer Prevention Research; Cancer Control Science; Early Detection and Community Oncology; Cancer Surveillance.

**Program Management and Support**

The program management and support budgets are used for the critical technical and administrative services required for NCI to carry out its extramural, intramural and cancer prevention and control programs. They include central administrative functions, overall program direction, grant and contract review and administration, personnel, program coordination and financial management.

## INTRAMURAL RESEARCH

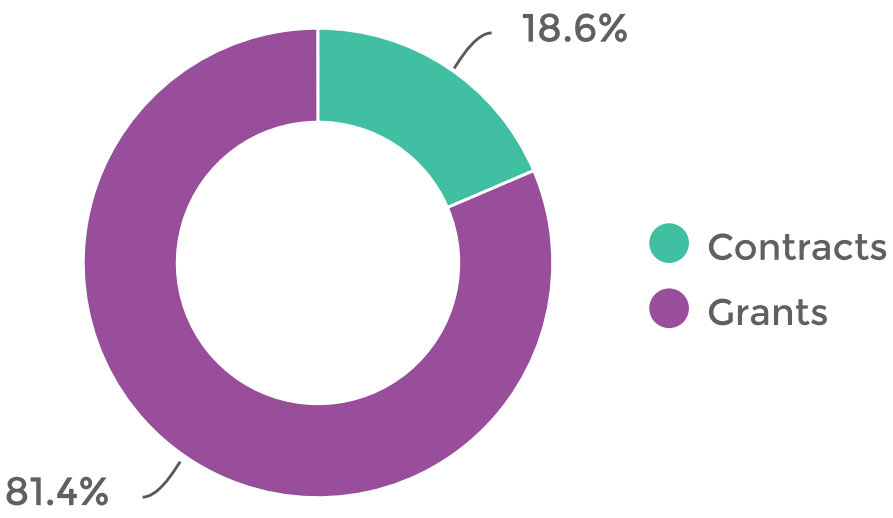
Research performed by NCI employees at the NIH is called Intramural Research. The NCI Intramural Research Program (IRP) consists of the Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG) and is dedicated to a comprehensive understanding of cancer. IRP Government scientists, research fellows, and visiting scientists from around the world conduct basic, clinical, population-based, and prevention studies. They also collaborate

with national and international investigators in academia and in the biotechnology and pharmaceutical industries to help expedite the application of new knowledge for the development and delivery of products that will benefit human health.

## EXTRAMURAL RESEARCH

Investigator-initiated extramural research is proposed and conducted by non-Government scientists in laboratories and clinical facilities throughout the country. This is the most important component of NCI's research program; nearly two-thirds of the Institute's budget is devoted to extramural research project grants as well as research and development contracts.

Figure 8: Total FY 2018 Extramural Funds

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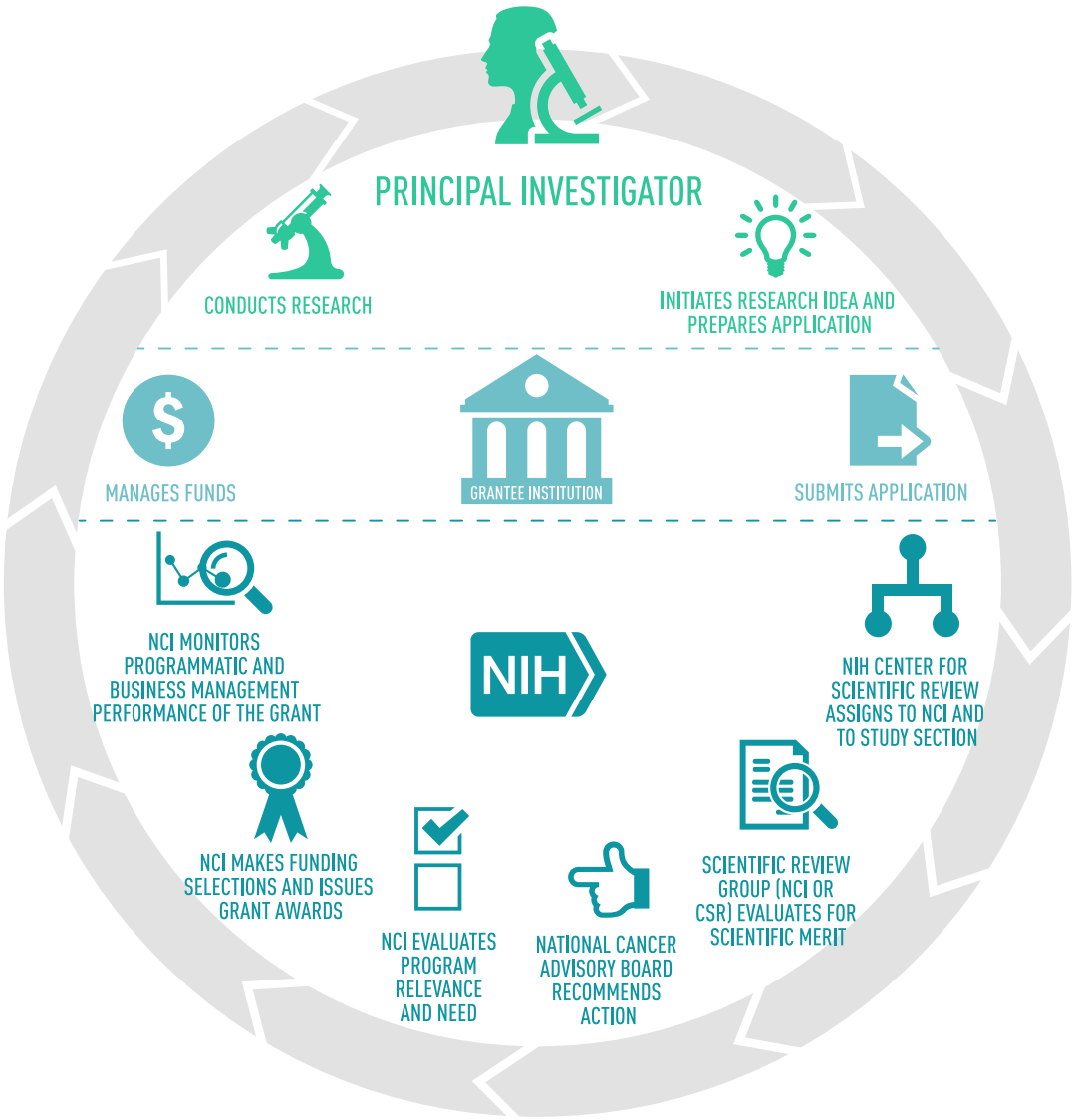
# GETTING STARTED: HOW TO FIND & APPLY FOR RESEARCH FUNDING

## Getting Started – The Basics

The NCI grants process is designed to ensure that applications proposing the most promising scientific research projects are evaluated and awarded. Here is some of the basic information you need to know as you begin learning about or navigating this important process.

Figure 9: Overview of the National Institutes of Health & National Cancer Institute Grants Process

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## Get Registered

Before you can apply for an NIH or NCI grant, there are several registration requirements. The organization applying for the grant must be registered with the federal government and have a unique entity identifier. They must also register with Grants.gov, the System for Award Management and the NIH eRA Commons. Principal Investigators (PI) must also be personally registered with the eRA Commons and 'affiliated' in the system with the applicant organization. Once a Principal Investigator is registered in the eRA Commons, that account remains active for them throughout their career, even if they change institutions or support more than one research institution's projects.

It's very important to register early! The process to register with each of the groups requires multiple steps and can take 6 – 8 weeks or more for a new organization. All registrations must be completed before the application deadline in order to submit.

For detailed information on registration requirements visit: https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply.htm

## How To Find Funding Opportunities

Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA) published on Grants.gov and/or in the NIH Guide for Grants and Contracts: grants.nih.gov/grants/guide.

"Investigator Initiated" or "unsolicited" applications are submitted to Parent Program Announcements that are mechanism specific.

In addition, the NCI may encourage the submission of grant applications through the publication of additional FOAs using one of the following solicitation types:

1. **Requests for Applications (RFAs):** Issued to invite grant applications in a well-defined scientific area to accomplish specific IC program objectives. The RFA identifies the specific receipt date(s), the estimated amount of funds earmarked for the initiative, the number of awards likely to be funded, and any specific criteria for scientific peer review. Applications received in response to a particular RFA are reviewed by an Institute's Scientific Review Group (SRG).
2. **Program Announcement (PA):** A formal statement about a new or ongoing extramural activity or program. It may note a continuing interest in a research area, describe modification in an activity or

program, and/or invite applications for grant support. Most PA applications are submitted with a standing receipt date and are reviewed with all other applications received at that time using standard peer review processes.

3. **Program Announcement Reviewed in an Institute (PAR):** Program announcements with special receipt, referral, and/or review considerations.

4. **Program Announcement with Set-Aside (PAS):** The NIH will occasionally publish a PAS, which is an announcement with set-aside funds.

5. **Notice of Special Interest (NOSI):** Used to announce interest in specific scientific research topics. Applicants cannot apply directly to a NOSI. When responding to a NOSI, they will be directed to use a parent announcement or other existing announcement to submit. It's important to include the NOSI notice number in the application. Over time, NOSIs will replace PAs.

## Funding Types

The NCI supports cancer research that spans the continuum from basic science to clinical research, to research on implementation, cancer control and cancer care delivery through an extramural program of grants, cooperative agreements, and research and development contracts.

### GRANTS

A grant provides federal financial assistance, including money, property, or both, to an eligible entity to perform approved scientific activities with little or no government involvement. Grants are used when:

1. No substantial programmatic involvement is anticipated between NCI and the recipient during performance of the financially assisted activities – this allows the recipient freedom of action in carrying out the independent research project

2. There is no expectation on the part of NCI of a specified service or end product for use by the NCI other than generating knowledge that moves cancer research and the mission of the NCI forward

### COOPERATIVE AGREEMENTS

A cooperative agreement is a support mechanism where the NCI and extramural scientists/clinicians work together during performance of the

research. Under this mechanism, the NCI and the extramural community are both responsible for ensuring the best and most important clinical research is conducted. Cooperative agreements are used when:

1. Substantial programmatic involvement is anticipated between the NCI and the recipient during the performance of the research activities
2. The applicant responds to a specific NCI announcement for cooperative agreements and must tailor the application to the announcement requirements

### RESEARCH AND DEVELOPMENT (R&D) CONTRACTS

The NCI uses R&D contracts to obtain cancer research services and other resources needed by the Federal Government. Contracts are legally binding documents and used when the principal purpose of the transaction is to acquire a specific service or end product for the direct benefit of or use by the NCI.

## Recipient Eligibility

NCI grants and cooperative agreements are only awarded to:

- Nonprofit organizations
- For-profit organizations
- Institutions of higher education
- Hospitals
- Research foundations
- State and local governments
- Federal institutions
- Individuals (fellowships only)
- Foreign institutions and international organizations (research grants only)
- Faith-based organizations

Each grant or cooperative agreement has its own eligibility guidelines that the awardee must meet for consideration. Any special criteria for applicant eligibility or requirements concerning the qualification of the principal investigator (PI) or other staff or participants is specified in the funding opportunity announcement (FOA), program guidelines, or other publicly available documents. Early Stage Investigators (ESIs): The NIH is committed

to promote the growth, stability and diversity of the biomedical research workforce. In order to support the next generation of researchers, we have established policies for those who qualify. Eligibility can be determined by entering the date of their terminal research degree or the end date of their post-graduate clinical training in their NIH eRA Commons profile prior to application submission.

## Research Settings

NCI-sponsored research takes place in the following three settings:

### LABORATORY

In the laboratory, research is pursued on the biology of cancer, the fundamental properties of cancer-causing agents and processes, and the body's defense against and response to cancer.

### CLINIC

In the clinic, patient-oriented research is carried out in prevention, detection, diagnosis, treatment, and rehabilitation.

### COMMUNITY

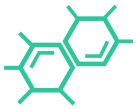
In the community, research is carried out on the causes, risks, predispositions, incidence, and behavioral aspects of cancer within the population.

Figure 10: NCI-Sponsored Research Settings

# NCI-SPONSORED RESEARCH TAKES PLACE IN THREE SETTINGS

## Laboratory

RESEARCHERS EXPLORE:



Biology of Cancer Research

Fundamental Properties of Cancer-causing Agents and Processes

The Body's Defense Against and Response to Cancer

## Clinic

RESEARCHERS FOCUS ON PATIENT-ORIENTED RESEARCH IN:

Prevention

Detection

Diagnosis

Treatment

Rehabilitation

## Community

RESEARCHERS FOCUS ON SPECIFIC ASPECTS OF CANCER WITHIN THE POPULATION, INCLUDING:

Causes

Risks

Predispositions

Incidence

Behavioral Factors

## Application & Solicitation Types

There are nine grant application types that may be used to identify the stages in the lifecycle of a grant. The grant type defines the procedures and specifies the documents required to process the grant award.

| | |
|---|---|
| **Type 1: New** | Request for support of a project that has not yet been funded. |
| **Type 2: Renewal (aka Competing Continuation)** | Request for an additional period of support based on a previously funded project. Competing continuation applications compete with other competing continuation, competing supplemental, and new applications for funds. |
| **Type 3: Competing Revision or Administrative Supplement** | Request for additional funds, either for the current operating year or for any future year previously recommended, to cover increased costs (noncompeting Administrative Supplement) or to expand the scope of work (Competing Revision). |
| **Type 4: Extension** | Request for additional time and/or funds beyond those previously awarded. Typically limited to certain mechanisms, including Merit (R37), Developmental/Exploratory (R21/R33), and Fast-Track Small Business Grants SBIR/STTR (R42/R44). These grants do not compete for available funds. |
| **Type 5: Noncompeting Continuation** | Request to pay next budget increment of a current award through Research Performance Progress Report (RPPR); does not compete for available funds. |
| **Type 6: Successor-in-Interest and Name-Change Agreements** | Request to pay next budget increment of a current award through Research Performance Progress Report (RPPR); does not compete for available funds. |
| **Type 7: Change of Grantee or Training Institution** | Request for support of a funded project to be transferred from one grantee or training institution to another. |
| **Type 8: Change of Institute or Center** | Change of NIH awarding IC for the Noncompeting continuation (Type 5) |
| **Type 9: Change of Institute or Center** | Change of NIH awarding IC for a Renewal (Type 2) |

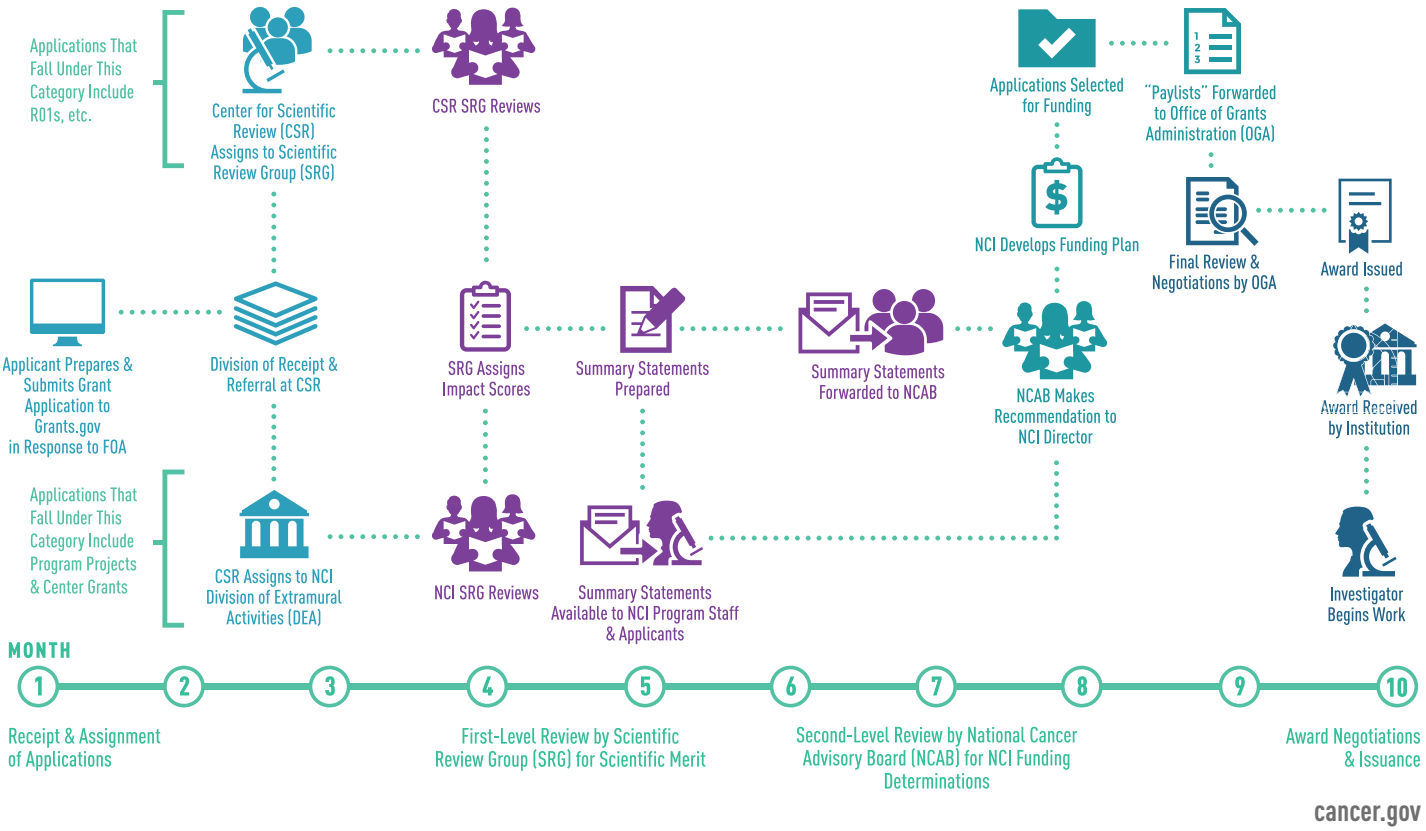
## How to Apply – Grant Application Development & Submission

Preparing and submitting your grant application is a major undertaking. Preparation time can range from two or three weeks for a small project application to as much as a year for a complex proposal. Take time to understand and review the process well in advance of submitting an application. The key is to be prepared and start as early as possible.

### PLANNING

Applying for grant funding is a highly competitive endeavor. To improve the odds of success, allow ample time to plan, organize and write the application. Use NIH's RePORTER tool (report.nih.gov) to search a repository of NIH-funded research projects and access publications. This tool will help determine the appropriate NIH IC to direct your application and show the types of projects funded in specific areas of science. You must submit your application in response to a specific FOA. Search

Figure 11: Grant Application Development, Submission, Review, & Award



for FOAs that are in your scientific field, be sure to follow the specific instructions and respond to any special review criteria. Examine the NIH and NCI's scientific mission, goals and objectives and address those in the application. Reach out to Program staff listed on the FOA for any questions regarding the proposed research scope and activities.

### WRITING YOUR APPLICATION

Writing a grant application is a major undertaking, planning and preparation are key. Some tips include soliciting feedback and review from colleagues and/or mentors on your research idea, make sure you have adequate preliminary data, review copies of successfully funded and completed NIH grant applications and become familiar with the peer review criteria. Be sure to demonstrate the high quality of the PD/PI, co-investigators, available research resources and the support from the institution. Build in adequate time for proof-reading and editing prior to submission.

## Allowable Costs

Research grant funds are awarded to supplement or complement the support of research at an institution. These funds are not intended to replace support already being furnished by the institution or for expenses previously incurred. Grant funds may be used for:

- Allowable direct costs specifically incurred in the conduct of the research project
- Facilities and administrative (F&A) costs (formerly known as indirect costs [overhead]) resulting from an institution providing support services

You must seek approval from the Program Director at least six weeks prior to submission if you anticipate submitting an application exceeding

$500,000 in direct costs in any year of the project.

If the requested amount is significantly greater than $500,000, you should receive approval even further in advance. Applications submitted in response to RFAs or other announcements that include specific budgetary limits are exempt from this requirement.

**Costs Reflected on the Notice of Award**

The NIH Notice of Award (NoA) includes both direct costs and applicable F&A costs, which are calculated by the Grants Management Specialist. Typically, this award reflects the maximum total costs provided during

the budget period even if a higher F&A rate is subsequently negotiated. If the amount required for F&A costs decreases because of either a new, lower negotiated rate or post-award budgetary changes in the direct costs of the grant, the excess F&A funds awarded generally may be rebudgeted to support allowable direct costs for the project, subject to specific requirements set forth in the applicable cost principles.

## SUBMISSION

Work with the Office of Sponsored Research (or central grants support office) so they may assist with planning and application submission. The FOA will provide discrete application forms, and deadlines or will refer to the NIH standard due dates. Late applications are generally not accepted. Electronic submission must be successful to Grants.gov by 5 p.m. local time (of the submitting organization) on the date indicated. Once an application is successfully transmitted to the NIH, the status of the application may be tracked online via the eRA Commons.

## INCOMPLETE SUBMISSIONS

The NCI considers a grant application incomplete if:

- It fails to follow the instructions provided on the appropriate application form
- It fails to follow specific instructions provided in an RFA or PA
- The material presented is insufficient to permit an adequate review
- The application is submitted after the receipt deadline – except in very rare cases.

Incomplete applications do not proceed further in the process and will not be reviewed.

Additional information on NIH Submission Policies may be found at: http://grants.nih.gov/grants/funding/submissionpolicies.htm.

Additional details and help for how to apply are available online: http://grants.nih.gov/grants/grants_process.htm.

## TRACKING YOUR APPLICATION

Once you have carefully compiled your application and it is ready for submission, the Authorized Organization Representative (AOR) or Signing Official (SO) will submit the application for the institution to Grants.gov. Here are some key points you need to know:

- Upon successful receipt of the application by Grants.gov, your AOR/SO will receive a Grants.gov Tracking Number that can be entered online to check the status.
- The NIH will retrieve your application from Grants.gov and process it into the eRA Commons where it will be checked for any submission "errors" or "warnings."
- Your application must be error free to move forward to the next phase and be considered for review.
- The organization is responsible for checking the eRA Commons to ensure the application was submitted successfully: http://era.nih.gov.
- The NIH will hold the application for two days (Monday-Friday, excluding federal holidays) to allow you to view the final assembled application exactly as a reviewer will see it.
- Both the AOR/SO and the PI should view the application and track its status in the NIH eRA Commons.
- The eRA Commons will send notifications to the AOR/SO and the PI upon receipt and as the application status changes—the applicant is responsible for checking the eRA Commons to ensure successful submission of the application.

## People Involved

### RECIPIENT

A grant recipient is an organization or individual awarded a grant or cooperative agreement by the NCI that assumes legal, financial, and scientific responsibility and accountability for both the awarded funds and the performance of the grant- supported activity.

### RECIPIENT INSTITUTION/ORGANIZATION

The recipient institution/organization is legally responsible and accountable for the performance and financial aspects of the grant-supported activity. The organization can be public or private, nonprofit or for-profit, or an educational institution, hospital, corporation, domestic or foreign agency, or other legally accountable entity. By accepting an award and its associated special terms and conditions, the grantee institution and the PI are responsible for using grant funds prudently and in accordance with cost principles for the purposes set forth in the approved application to conduct the research.

## INSTITUTIONAL BUSINESS OFFICIAL (BO)

Person working in a research organization's business office who has signature or other authority. That person is the same as the Grants.gov Authorized Organizational Representative (AOR) and the eRA Commons Signing Official (SO).

## PRINCIPAL INVESTIGATOR (PI)

The Principal Investigator (PI) is the individual designated by the recipient organization to direct the project or activity being supported by the grant. He/she is responsible and accountable to recipient organization officials for the proper conduct of the project or program. The organization is, in turn, legally responsible and accountable to NCI for the performance and financial aspects of the grant-supported activity.

## PROGRAM DIRECTORS/PROGRAM OFFICERS

The NCI extramural Program staff are each assigned responsibility for a certain programmatic and scientific approach to cancer research. Program Directors collaborate closely with Grants Management Specialists in the Office of Grants Administration providing oversight of the NCI grants program. In general terms, the Program Director is responsible for the programmatic, scientific and/or technical oversight of his/her portfolio. Primary responsibilities fall into categories including:

- Program Planning: may include choosing new areas of science for emphasis and associated feasibility studies, identifying areas of research that are under-served, exploiting advances in biomedical knowledge, establishing scientific goals and working with a variety of panels, consultants, scientific review groups, councils, boards etc.
- Program Development and Implementation: ensures the most effective use of federal funds by allocation of research support among competing scientific areas. Assessing a project's individual scientific quality but also its contribution to the overall program strategy and the IC's strategic plan. Presenting a prioritized list of activities for program implementation.
- Program Relevance: review individual application assignments within the IC to ensure the most appropriate program areas are assigned for evaluation and consideration.
- Scientific merit/initial peer review – Program Directors play an ancillary role by attending scientific merit reviews to witness the discussion of the application, especially in relation to other applications.

- Program Management: includes all the activities and responsibilities surrounding the award of a grant and continue throughout the lifecycle of the award. Project monitoring, review of progress, completion of the program checklist (referred to as the Greensheet at NCI) and assurance of adherence to laws, regulations and policies. Program management is accomplished by working closely with the principal investigator at the institution and the grants management specialist.
- Program Analysis, Reporting and Evaluation: includes cumulative, current and projected program activities using an objective, qualitative and quantitative method. The reporting is essential for congressional justification, program support and any modifications.

## SCIENTIFIC REVIEW ADMINISTRATOR OR OFFICER (SRA OR SRO)

A federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The Scientific Review Administrator (SRA) serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

In the context of contract proposals, the SRA is the NIH official who has the responsibility to ensure that Research and Development (R&D)/In Support of R&D contract proposals receive a competent, thorough and fair peer review by the Scientific Review Group (SRG). The SRA organizes and provides scientific/technical support to an SRG, and is responsible for the documentation/contents of the SRG minutes, including votes on acceptability or unacceptability and scoring of the proposals, and other recommendations, to the Project Officer and Contracting Officer.

## NCI GRANTS MANAGEMENT OFFICER (GMO)

The Grants Management Officer (GMO) is responsible for all business management aspects of grants and cooperative agreements, including review, negotiation, award, administration, and for the interpretation of grants policies and provisions. The GMO is responsible for:

- Advising and assisting management and program staff in developing, implementing, and evaluating program plans, strategies, regulations, announcements, guidelines, and procedures
- Serving as the focal point for receiving and responding to all correspondence from recipients related to business management activities, such as requests for prior approval required by terms of award or by policy, or requests that could result in a change in the

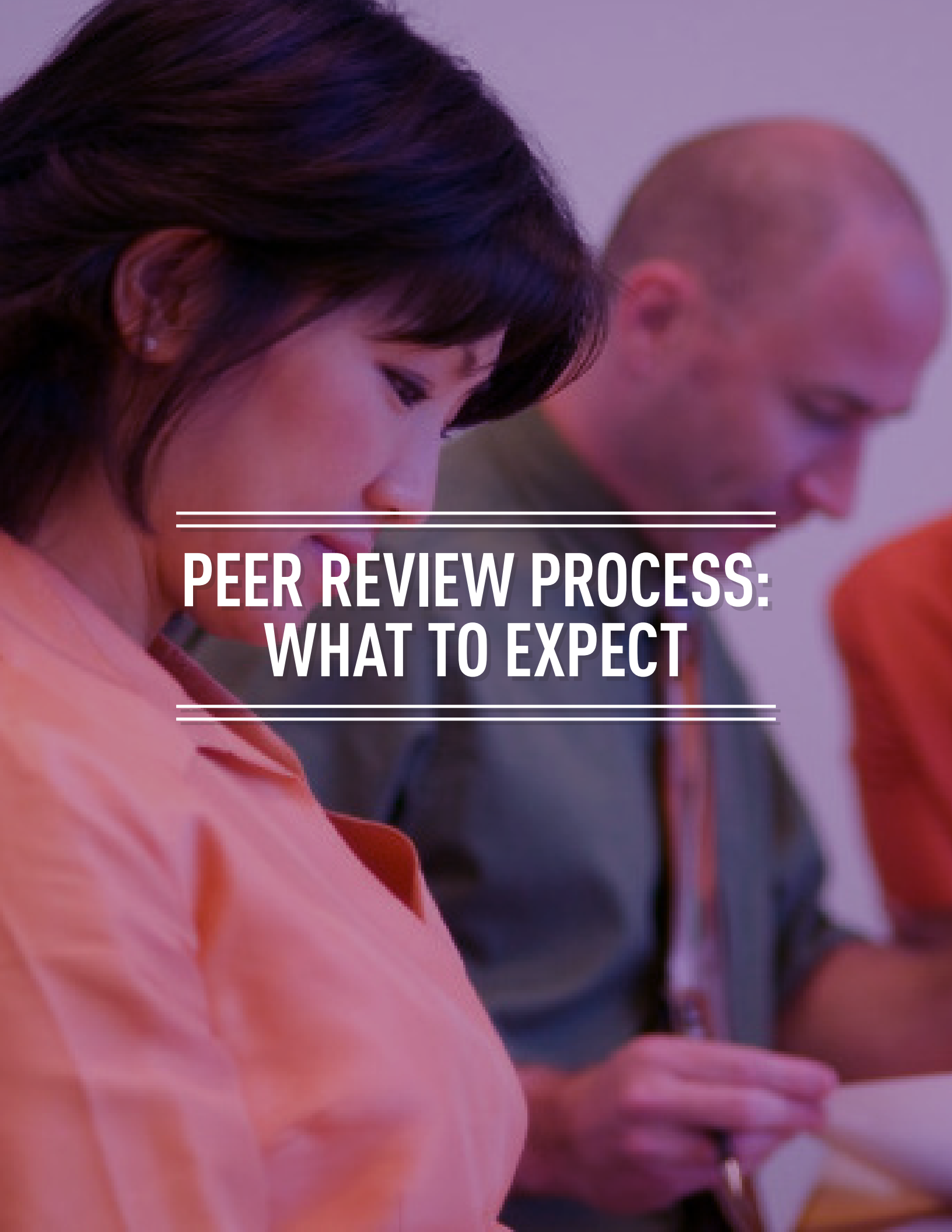
awarded amount

- Reviewing grant applications from a management point of view for conformity to laws, regulations, and policies
- Negotiating grant budgets and issuing awards; only staff with GMO authority is able to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH
- Providing business management consultation and technical assistance on grant matters to internal staff, applicants, and grantees
- Resolving audit findings involving the NCI grants program and/or commenting on findings before the agency's official position is made known to the grantee
- Providing continuing surveillance of the financial and management aspects of grants through reviews of reports, correspondence, site visits, or other appropriate means

### GRANTS MANAGEMENT SPECIALIST

The Grants Management Specialist is an individual selected by the Grants Management Officer to oversee the business and other non-programmatic aspects of a portfolio of grants and cooperative agreements. The GMS evaluates grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiates grants; provides consultation and technical assistance to grantees, administers and monitors grants after award. The GMS also serves as the day-to-day point of contact for the grantee if they have administrative questions. Grants Management staff perform many activities but a few of the more common include:

- Processing administrative supplements
- Extending grant periods (with and without additional funds)
- Reviewing financial management reports
- Monitoring Projects
- Rebudgeting
- Reviewing Audit Reports
- Assisting Program staff with Grant Closeout
- Processing changes in Principal Investigator or grantee institution



# PEER REVIEW PROCESS: WHAT TO EXPECT

## Application Receipt, Referral & Peer Review

After planning, developing and submitting a grant application, the Division of Receipt and Referral in the Center for Scientific Review (CSR) reviews the application for completeness, determines the area of research and assigns the application to an Institute or Center (IC) for review and funding consideration based on the focus and mission of the IC. The application is then assigned to either a Scientific Review Group (SRG) within CSR or to the NCI Division of Extramural Activities (DEA for review. When an application is assigned to NCI, a referral officer will examine and direct it to the appropriate NCI program director.

### GRANT NUMBER

Before starting the peer review process, each new application received is assigned an identification number (grant number).

| Application Type | Activity Code | NIH Admin Organization | Serial Number | Support Year | Suffix Code |
|---|---|---|---|---|---|
| **1** | R01 | CA | 100228 | 01 | A1 or S1 |

- Application Type: Indicates whether the application is new, a renewal (competing continuation), noncompeting, or other type. The example shows a new (Type 1) application.
- Activity Code: Lists the type of grant (grant mechanism) that has been applied for; an (R01) is a traditional research project.
- Administering Organization: A two letter abbreviation for the primary NIH IC assigned. CA is the two-digit code for NCI.
- Serial Number: a unique five or six digit number that identifies the specific application and indicates that it is the 100,228th application assigned to the NCI.
- Support Year: Indicates the current year of support. For example, the 01 shows that this is a new grant. Sometimes the support year is followed by a suffix.
- Suffix Code: Starts with an “A” to indicate an amendment to the application. An A1 is the first revised or amended application. An “S” suffix code is used to show supplements. For example, an S1 is for the first supplement.

## Peer Review

The NIH peer review system consists of two sequential levels of review mandated in 1974 by Section 475 of the Public Health Service Act. This dual review process provides a more objective evaluation than a single level of peer review by guaranteeing that the members of the scientific research community evaluate the project's scientific and technical merit.

## First Level of Review

The first (initial) level of review is performed by either the NIH Center for Scientific Review (CSR) or NCI. Peer review meetings are closed sessions. All attendees must have permission to be present. Within the NCI, the Division of Extramural Activities (DEA) organizes and manages the chartered SRG peer review of grant and cooperative agreement applications that are highly mission specific to the institute. These include applications for program projects, Cancer Center Support Grants (CCSGs), multisite clinical trials, the NCI's Clinical Trials Cooperative Groups, Ruth L. Kirschstein National Research Service Award (NRSA) grants, and cancer education grants.

Sometimes Special Emphasis Panels (SEPs) are formed to conduct reviews of applications that cannot be reviewed by an SRG or chartered NCI review committee due to conflict of interest or lack of expertise. NCI SEPS usually evaluate NCI Requests for Applications (RFAs) and Program Announcements Reviewed in an Institute (PARs). The composition of the panel is determined by the expertise needed to evaluate the submitted grant applications.

## Peer Review Criteria

**Overall Impact** – Reviewers provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following core review criteria, and additional review criteria (as applicable for the project proposed).

**Scored Review Criteria** – Reviewers consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field. Clinical Trials research has additional questions and review criteria.

- Significance
- Investigator(s)
- Innovation
- Approach
    - Study Design (Clinical Trials)
    - Data Management and Statistical Analysis (Clinical Trials)
- Environment

**Additional Review Criteria** – In addition to the above criteria, in accordance with NIH policy, reviewers will evaluate the following additional items in the determination of scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items:

- Study Timeline (Clinical Trials)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Protection for Vertebrate Animals
- Biohazards
- Resubmission
- Progress (for Type 2 Renewal applications)
- Revision

Reviewers will also additionally consider:

- the budget and period of support
- select agent use and procedures
- applications from foreign organizations
- resource sharing plans
- Authentication of key biological/chemical resources

The possible recommendations by the review committee are one of the following:

- Scoring
- Not discussed (ND)

- Not recommended for further consideration (NR)
- Deferral (DF)

All actions require a majority vote. In the event of a split vote (i.e., when two or more IRG members disagree with the majority), the recommendation is based on the majority vote, but the minority opinion is recorded in the Summary Statement. An application may be deferred if additional information is needed to make a definitive recommendation.

## Impact/Priority Scores

This score is assigned by reviewers to indicate the scientific and technical merit of the application. Scores range between 1 (exceptional) and 9 (poor). The score is a reflection of the reviewer's assessment of the overall impact the project could have on the field.

After the review meeting, the SRO will determine the final overall impact score by calculating the mean score from all the eligible members' impact scores, and multiplying the average by 10; the final overall impact score will be reported on the summary statement. Thus, final impact scores range from 10 (high impact) through 90 (low impact). Numerical impact scores will not be reported for applications that are not discussed.

## Summary Statements

Immediately after the meeting, the SRO prepares individual reports summarizing the recommendation for each application, called Summary Statements. The Summary Statement is available online in the eRA Commons for the PI within 30 days of the meeting. For new investigators submitting an R01 application, the Summary Statement is posted within 10 days of the meeting.

The Summary Statement consists of:

- Contact information for the Program Officer handling the application
- Overall impact score and percentile (if applicable)
- Brief summary of the discussion (only for applications that are discussed)
- Reviewer critiques and individual criterion scores
- Committee recommendations concerning the budget
- Official meeting roster

## Just-In-Time Requests

For applications reviewed by the Center for Scientific Review (CSR) and scored within a certain range, the NIH automatically sends an email requesting the following Just-in-Time (JIT) information:

- Updated other support for senior/key personnel – Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution identified for the current application. It also includes resources and/or financial support from all foreign and domestic entities,
- Certification of Institutional Review Board (IRB) approval for the use of human subjects (if applicable)
- Required Education in the Protection of Human Subjects
- Certification of Institutional Animal Care and Use Committee (IACUC) approval (if applicable)

**JIT requests are neither a Notice of Award nor a guarantee of funding.** JIT information must be submitted electronically using the Just-in-Time feature in the eRA Commons. It must be received and evaluated prior to an award being made.

## Second Level of Review – National Cancer Advisory Board (NCAB)

The second level of review for NCI programmatic relevance is performed by the National Cancer Advisory Board (NCAB). The NCAB is the principal advisory body for the NCI and its members are appointed by the President.

### LEGISLATIVE AUTHORITY

The NCAB was chartered in 1973 by the Federal Advisory Committee Act (P.L. 92-463) and the Board is rechartered every 2 years. The National Cancer Act of 1971 (P.L. 92-218) and the Health Research Extension Act (P.L. 99-158) specify that two-thirds of the NCAB members be appointed from among the leading representatives of the health and scientific disciplines relevant to cancer. The remaining one-third shall be appointed from the public and include leaders in public policy, law, health policy, economics and management.

The NCAB is responsible for the final external review of all grant applications and cooperative agreements referred to the NCI except for

the following:

- Those domestic applications requesting $50,000 (or less) in direct costs per year (without human subject, animal welfare, minority/ gender/ children, or biohazard concerns)
- Individual fellowship applications
- Applications with percentiles in the bottom half of those reviewed by CSR
- Applications not recommended for further consideration (NRFC)

## NCAB Meetings

The NCI Director or the Board Chair calls a meeting with NCAB no fewer than four times a year, and the meetings usually last two days. Meetings of the NCAB that are scheduled for January/February, May/June, and September/October include application review. The November/December NCAB meeting is reserved for review of NCI programs.

NCAB meetings are open to the public when general program activities and plans are discussed. By the Department of Human and Health Services (DHHS) regulation, scheduled NCAB meeting dates are published well ahead of time in the Federal Register.

Attendance at the closed grant application review sessions is limited to NCAB members, SROs, the NCI Director, appropriate NCI staff, and designated representatives of the Secretary, DHHS. SROs and appropriate NCI staff members attend NCAB meetings to provide, when necessary, specific details or additional information on projects under discussion by the NCAB.

### EXPEDITED NCAB REVIEW

An expedited NCAB approval process is used for percentiled R01s reviewed by CSR and for all R21s, except:

- Those applications submitted in response to an annoucement with a set- aside.
- Applications with foreign institution involvement.
- Applications whose summary statement expresses concerns with regard to human subjects, animal welfare, biohazards, or inadequate representation/justification of gender/minorities/children.

### RECOMMENDATIONS

Once it has acted on those applications given special attention, the NCAB considers a motion for en bloc concurrence with the SRGs' recommendations as presented in the summary statements. NCAB members do not attend discussions or vote on applications from their own institutions or affiliated institutions and are required to sign conflict-of-interest statements. This allows them to participate in the en bloc concurrence without risking a conflict of interest.

## Post-NCAB Meetings and Funding Decisions

After each NCAB meeting, NCI staff members meet to discuss and review the NCAB's recommendations. The NCI Scientific Program Leadership (SPL) approves the funding plans for all RFAs and other special initiatives. Applicants who will be funded are subsequently notified at the time of the award negotiation.

### NCI FUNDING DETERMINATIONS

Early in the fiscal year, the NCI Scientific Program Leadership Committee (SPL) formulates funding guidelines for programs based upon expected allocations of funds, program requirements, and prior history. The funding mechanisms are reevaluated prior to each grant review cycle and adjusted to the current level of funds available and future funding.

The Committee considers the following:

- Congressional mandates
- New scientific opportunities
- New initiatives
- Program priorities
- Previous commitments, such as noncompeting continuations
- Other projected needs
- Anticipated availability of funds

Final allocations and funding decisions cannot be made until the actual amount of the federal appropriation is known.

After review and discussion with the NCI Division, program and grants management, it becomes an authorization (paylist). The chief GMO and grants management staff use this paylist as the authority to complete the administrative review, negotiation, and award process.

## Appeal of a Review Recommendation

If the principal investigator believes that the review was affected by bias, conflict of interest, insufficient or inappropriate expertise, or factual errors, he/she may appeal the recommendations of the committee. The Authorized Organization Representative (AOR) must concur with the request for appeal.

Applicants who disagree with the assessment of the review group may contact the Program Director to discuss the Summary Statement and the situation relative to the application. Most often, the applicant revises and resubmits the application.

## Options if Your Application Isn't Funded

If the application isn't funded, there are three basic options: revise and resubmit, create a new application or apply outside of NIH. Speak to your Program Director for their expertise and insight. If you decide to resubmit, you should know that there are unique rules. Be sure to review the requirements.

For more details on Peer Review: https://grants.nih.gov/grants/peer-review.htm

For more information on the Resubmission Policy, visit the webpage: http://grants.nih.gov/grants/policy/amendedapps.htm.

# GRANTS ADMINISTRATION: A TEAM APPROACH

Many more grants are approved by the National Cancer Advisory Board (NCAB) than can be financed from the NCI budget. This means that NCI staff must work closely to ensure that the selection of grants for funding, the programmatic support and the awards negotiation and funding levels are carefully determined and administered.

## Office of Grants Administration (OGA)

The NCI's Office of Grants Administration (OGA) is the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NCI. The OGA staff ensures that the recipient and the NCI fulfill and comply with all legal requirements, regulations, and administrative policies.

The OGA consists of the Director's Office, three Grants Administration Branches, and the Business Operations Branch. Although the Director's Office and each branch have their own responsibilities, all staff work together to help build, maintain, and enhance a cohesive and comprehensive cancer research agenda.

### OFFICE OF THE DIRECTOR, OGA

The Office of the Director provides leadership, direction, and operational oversight of the OGA. Within the Office of the Director is also the NCI-designated Chief Grants Management Officer (CGMO). The CGMO is the principal Grants Management Officer (GMO) who is responsible for all business and fiscal management of the NCI grant portfolio. The CGMO has the authority to appoint and exercise line authority over additional GMOs.

### RESPONSIBILITIES

- Monitors the financial assistance process to ensure that all required business management actions are performed by the awardee and the government in a timely manner both before and after award
- Evaluates and monitors the business management capability and performance of applicant organizations and awardees, as well as the internal operating procedures associated with the business management aspects of the financial assistance process
- Interprets and develops financial assistance policy

### GRANTS MANAGEMENT BRANCHES

Each OGA grants management specialist manages nearly two hundred grants. To ensure quality control and the highest level of service for NCI

grantees, rigorous internal controls and auditing are performed. Multiple levels of review and oversight are standard protocol. OGA has three grants management branches consisting of a branch chief, multiple team leads, and grants management specialists.

The branch chiefs and team leads serve as liaisons within NCI for specific cancer research activities, while most grants management specialist assignments are organized by extramural institution. This facilitates an in-depth understanding of the grantee's business administration practices and develops strong collaboration. It also minimizes the requests for duplicative institutional information and oversight across OGA for each institution.

Grants Management Specialist assignments by institution are posted online at: http://www.cancer.gov/grants-training/grants-management/contacts.

## Award Negotiation & Issuance

When an agency awards a grant, it is formalizing its partnership with the recipient (institution) to ensure compliance with federal laws, regulations and policies. This protects the overall scientific endeavor. Timely and effective communication between a recipient and the NCI staff is critical throughout the pre-award, award and post-award processes.

Once an application has been reviewed and accepted for funding, there are multiple pre-award activities that happen before the award can be made and accepted. Additional information must be collected and evaluated to determine the institution and research staff's readiness, as well as compliance to policy requirements and the final determination of budget and award amount.

## Pre-Award Activities

After preliminary funding decisions are made, NCI program directors complete their programmatic, scientific and/or technical review of each assigned application. As a result of this review, program directors may contact applicants to request additional or updated information regarding various issues, such as:

- Other support – documentation should include all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution

identified for the current application. It also includes resources and/or financial support from all foreign and domestic entities

- Overlap with other projects
- Resolution of scientific concerns expressed by the initial reviewers regarding the involvement of human subjects
- Use of live vertebrate animals
- Minority and gender representation
- Potential biohazard problems
- Public Access compliance

Grants management staff may contact applicants to request additional information regarding assurances and certifications or missing application documentation that was not received or is outdated from a Just-in-Time (JIT) submission.

The grants management specialist and program director continually work together throughout this pre-award phase of the award process. Program directors document their review and resolution of problems by completing and submitting to the grants management specialist a signed checklist for each application to be funded.

## Grants Management Review

After receiving notification from the program director and verifying selection for funding, the Office of Grants Administration staff (grants management specialist) begins the process of reviewing the application for their assigned institutions from a business/administrative management perspective.

This includes a review of the application, peer review recommendations, all applicable material and the programmatic comments and recommendations. The grants specialist is reviewing for conformity to laws, regulations and policies as well as determining if any special conditions are required prior to award. This review also involves a cost analysis of the proposed categorical budget, if applicable; a review for administrative compliance with the Department of Health and Human Services (HHS) and NIH policies, and negotiations with the grantee's business official and/or the principal investigator.

### COST ANALYSIS

The grants management specialist reviews applications that include

categorical budgets for:

- Reasonableness of costs
- Adherence to cost principles
- Relationship of costs to the proposed project
- Financial management capabilities of new applicant institutions
- Similarity to or duplication of existing programs or projects being supported by other sources (to the extent that this can be ascertained)
- Specific requirements established by a particular program (e.g., conference or training grants)

The extent of this analysis is a matter of judgment, based on factors such as:

- The applicant's previous experience in managing grant funds
- The NCI's experience with the grantee
- The dollar amount of the grant
- The complexity of the grant
- The financial history of the project
- NCI program concerns

### ADMINISTRATIVE REVIEW

In addition to analyzing the budget, the grants management specialist determines that all necessary assurances and reporting requirements have been met and that the applicant is in compliance with all appropriate rules and policies as well as NIH and DHHS requirements. The following is a brief itemization of some of the issues that must be addressed, when appropriate, before an award can be issued:

- Compliance with 45 CFR Part 46, "Protection of Human Subjects"
- Certification of required education in the Protection of Human Research Participants
- Compliance with HHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions
- Civil rights, handicapped individuals, and sex and age discrimination assurances

- Compliance with Data and Safety Monitoring requirements
- Civil rights, handicapped individuals, and sex and age discrimination assurances
- Compliance with Data and Safety Monitoring requirements
- Debarment, suspension, and voluntary exclusion certification
- Drug-free workplace certification
- HHS-approved entity identification number (EIN) for the applicant institution
- Facilities and Administrative (F&A) costs—also known as Indirect Costs
- Federal Financial Reports (FFRs)
- Invention statements
- Lobbying certification and disclosure
- Assessment of applicant institution's management capability
- Appropriate choice of mechanism (grant/contract/cooperative agreement)
- Misconduct in science assurance
- No delinquency on federal debt certification
- Peer review recommendations
- Administrative notes from peer reviewers on the summary statement
- Program income
- Availability of proposed project staff
- Scientific and budgetary overlap with other support
- Time and effort over-commitment
- Involvement with human embryonic stem cells (hESC)
- Compliance with public access requirements
- Financial conflict of interest (FCOI)

## NEGOTIATION

The primary purpose of negotiating an award is to establish the appropriate funding level and period of performance, resolve identified problems, and agree on specialized terms and conditions of award, if

needed. The degree and form of the negotiation depend on a variety of factors, such as the dollar amount and complexity of the project, nature of the problems identified, and fulfillment of new recipient requirements. The grants management specialist can usually complete negotiations and obtain needed information through correspondence with the applicant institution. However, it may become necessary for NCI staff to visit the applicant institution to address certain issues or problems.

Initial peer review recommendations, budget/programmatic modifications and determination of facilities and administrative (F&A) costs are all components of the pre-award negotiation process.

## PREPARATION OF AWARDS AND OBLIGATION OF FUNDS

The Notice of Award (NoA) is the legal notification to the recipient that the project has been awarded and that funds may be requested from the HHS Payment Management System (PMS).

The NoA includes multiple sections related to terms of award. Section II includes reference to the NIH Grants Policy Statement (NIH GPS) as a term and condition for all awards. It contains the legally binding requirements for all grant recipients. Section III lists standard terms and Section IV contains special terms and conditions specific to the NCI and/or the particular grant. Recipients must pay careful attention to the terms and conditions of an award, particularly any specific to the grant. If recipients violate the terms and conditions of an award, NIH may place a restriction on the award, institute special monitoring procedures, or take other enforcement actions.

Once the NoA is signed by the grants management officer (GMO), it is transmitted via email and posted in the NIH eRA Commons. In addition to the terms, the NoA includes:

- The name and address of the recipient institution
- The title of the project
- The name of the principal investigator
- The period of performance
- The amount recommended for future years of support
- Contact information for the assigned program director and grants management specialist

In addition, all competing/noncompeting award notices, except those

in the modular Streamlined Noncompeting Award Process (SNAP) populations, show the authorized direct costs by budget category (e.g., personnel, supplies). The NoA provides approval for the expenditure of funds agreed upon during negotiations. Associated facilities and administrative (F&A) costs are also included on the NoA.

If the awarding office has determined that a prospective recipient is financially unstable, has a history of poor performance, or has a management system that does not meet the agency's standards, the awarding office may impose restrictive terms and conditions. The awarding office may also delay issuing the award until all the agency's standards have been satisfied.

By signing the grant award, the grants management officer certifies that:

- The choice of the award mechanism is appropriate under applicable policy
- The application was properly peer reviewed
- The award amount is accurate and appropriate for the grant-supported activity
- The applicant institution is judged to have (or is expected to acquire) adequate business management capability to administer the grant and account for federal funds
- The award is being made consistent with the terms and conditions specified for the particular program and the appropriate review recommendations
- The award is consistent with governing legislation, regulations, and policies
- All review and award actions are clearly documented in the official grant file

The award amount is forwarded to the NIH Office of Financial Management where it is recorded as an obligation in the NIH official financial system.

The NoA is issued for the initial budget period. If subsequent budget periods are also approved, the NoA will include a reference to those budgetary commitments. Funding for subsequent budget periods are generally provided in annual increments following the annual assessment of progress. This funding is also contingent on the availability of funds.

## CONGRESSIONAL NOTIFICATION

For all new, renewal and competing supplement awards, there is a statutory requirement that Congress be notified prior to the issuance of an award. If the award exceeds $1 million, the White House may also be informed.

## ACCEPTANCE OF AWARD

The recipient indicates acceptance of the terms and conditions of an award by drawing down or otherwise obtaining funds from the grant payment system. By accepting the award, every grant recipient agrees to comply with all terms and conditions of award incorporated by reference into the NoA.

## AWARD PAYMENT

To minimize the impact of cash withdrawals on the public debt level and to reduce related financing costs, the U.S. Department of the Treasury issued regulations governing the flow of cash to recipient organizations. Specifically, grantees should not request funds until actually needed for disbursement purposes.

Grant payments are administered by the Department of Health and Human Services (DHHS) Payment Management System. Funds are deposited directly into the recipient's bank account on the next business day.

## FUNDING CONSIDERATIONS

Although a specific dollar amount is indicated on the NoA for each future year of recommended support, the amount awarded is subject to the availability of funds appropriated for the fiscal year, as well as other considerations related to scientific progress and the recipients rate of expenditure of grant funds. Grants may be negotiated and awarded for less than the recommended level. Conversely, when the recipient can justify the need for additional funds, the NCI has the authority to grant the increase as long as the approved scope of the project is not being expanded.

If the recipient wants to request additional funds to expand the scope of the project, a competing supplemental application must be submitted according to established deadlines. These applications undergo dual review and compete for funds with all other investigator-initiated competing applications.

# POST-AWARD & CLOSEOUT

## Important Legal Obligations

There are many requirements that recipient organizations need to be aware of to ensure they are successful stewards of federal funds. NIH publishes policy updates in the NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide) as well as updates to Funding Opportunity Announcements (FOAs).

You should reference the NIH Grants Policy Statement (http://grants.nih. gov/grants/policy/nihgps) and the Notice of Award (NoA) often for details on all post-award processes and requirements.

### MONITORING

The grants management specialist (GMS) and program director continuously monitor the grants in their portfolio through the review and assessment of information gathered from audit reports, progress reports, financial reports, site visits, correspondence, and peer review.

Recipients are required to have financial systems in place to monitor their grant expenditures. NCI grants management staff monitors individual grants within each budget period and within the overall project period. The rate and types of expenditures are expected to be consistent with the approved project and budget based on an assessment of the effort to be performed during that period. The GMS reviews recipient cash expenditure reports to determine whether they indicate a pattern of accelerated or delayed expenditures. Expenditure patterns may indicate a deficiency in the recipient's financial management system or internal controls. Accelerated or delayed expenditures may result in a recipient's inability to complete the approved project within the approved period of performance. NCI allows some flexibility for rebudgeting, but there are specific guidelines and limitations.

The names, titles, and telephone numbers of the responsible GMS and program director are included in the NoA.

Under federal regulation 45 CFR 75.364, the HHS awarding agency, Inspector General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the grant awards in order to make audits, examinations, excerpts, transcripts, and copies. The recipient is also required to allow timely and reasonable access to personnel for the purpose of interviewing and discussing these documents. The rights of access are not limited to the required retention

period, but last as long as records are retained.

When problems or weaknesses are found, NCI staff work with the applicant or the recipient institution to resolve the issues. It is usually possible for a mutually agreeable course of action to be worked out so that the award process can proceed. However, it may be necessary for the grants management officer (GMO), designated specialist, and/or program director to visit the applicant or recipient institution(s) in order to evaluate scientific progress, management systems, and adequacy of policies, procedures, and controls if:

- Problems or weaknesses are found to be severe enough to threaten the ability of the principal investigator or the recipient institution to administer and/or complete the research project for which the grant was awarded
- The applicant organization refuses to adopt required assurances and certifications that reflect national social and economic policy
- The applicant fails to comply with the terms of award. NCI staff may then take any of the following actions:
    - Not issue the new or competing renewal award
    - Withhold the next noncompeting renewal award
    - Adjust the level of support awarded
    - Place restrictions and/or special conditions on the award
    - Pay grantees on a reimbursement rather than an advance basis
    - Suspend or terminate the active grant

## PRIOR APPROVAL REQUESTS

In general, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the grantee's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a grantee makes certain budget modifications or undertakes particular activities.

Circumstances in which prior approval is required include but are not limited to:

- a change in scope of the project,

- extensions beyond the allowable 12 month period,
- if the transfer would be to a foreign component,
- change in status of key personnel,
- change of recipient organization,
- deviation from award terms and conditions,
- foreign component added to a grant to a domestic organization,
- or a need for additional NIH funding.

All requests that require prior approval must be submitted to the grants management officer at least 30 days before the proposed change. Recipients are encouraged to use the Prior Approval module within the eRA Commons system to streamline the submission and approval process.

If the Authorized Organization Representative (AOR) is not sending the request, it must be endorsed by him/her; a cc to the AOR is not acceptable. Requests must be clearly identified as prior approval requests and include the grant number. The GMO will review the request and provide a response to the AOR with copies to the PD/PI and the NCI program director. Only responses from the GMO are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk.

Failure to receive prior approval may result in enforcement action such as the disallowance of costs or termination of award or other actions within agency authority. Questions should be directed to the grants management specialist designated in the NoA.

For more information: The NIH Grants Policy Statement defines what items require prior approval. https://grants.nih.gov/policy/nihgps/index.htm

## Reporting Requirements

Recipients must submit a variety of reports during the lifecycle of a grant award. All reports must be accurate, complete, and submitted on time. Below is a list of the most common reports required, but it is not all-inclusive. Recipients must review their individual award requirements and the NIH Grants Policy Statement to ensure compliance.

## RESEARCH PERFORMANCE PROGRESS REPORT (RPPR)

A (RPPR) is required at least annually as part of the non-competing continuation (Type 5) award process and it must be submitted through the eRA Commons. Only the PI or their delegate may initiate an RPPR in the eRA Commons. If there are multiple PIs, only the Contact PI (or their delegate) may initiate the report. The report must be submitted and approved by NCI Program and Grants Management staff prior to receiving funding for each subsequent budget period within a previously approved competing project period. The Notice of Award (NoA) will specify if a progress report is due following a different schedule.

## WHO REVIEWS PROGRESS REPORTS?

Program directors review the RPPR to determine whether scientific progress is adequate to justify continued support in non-competing years. When all requirements are satisfied, an award for the next budget period is issued. This process is repeated each year of the project period.

Grants management specialists review all noncompeting progress reports, including those in the Streamlined Noncompeting Award Process (SNAP) population. The basic principle of the SNAP award is that total costs for the entire competitive segment are negotiated at the time of the initial competing award, thus eliminating the need to engage in annual total cost negotiations. As part of that negotiation, NCI staff ensure that proposed costs are allowable, allocable, reasonable, and necessary for the project. SNAP applications must include answers to the following three questions:

- Has there been a change in the “other support” of key personnel since the last reporting period?
- Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Award from what was approved for this project?
- Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year’s total budget?

If responses to these questions are not readily apparent or are incomplete, the NCI sends a letter to the recipient business official requesting that the required information be provided in writing.

It is important to note that submitting RPPRs on time, but without required information, results in extra work for both NCI staff and the grantee. In addition, the submission of incomplete applications

frequently delays issuance of an award.

## FUNDING CONSIDERATIONS WITH THE PROGRESS REPORT

Although a specific dollar amount is indicated on the NoA for each future year of recommended support, the amount awarded is subject to the availability of funds appropriated for the fiscal year, as well as other considerations related to scientific progress. Grants may be negotiated and awarded for less than the recommended level. Conversely, when the recipient can justify the need for additional funds, the NCI has the authority to grant the increase as long as the approved scope of the project is not being expanded.

If the recipient wants to request additional funds to expand the scope of the project, a competing supplemental application must be submitted according to established deadlines. These applications undergo dual review and compete for funds with all other investigator-initiated competing applications.

## RPPR DEADLINES

RPPRs for awards subject to SNAP (Streamlined Non-Competing Award Process) are due the 15th of the month preceding the month when the budget period ends. Fellowship and Non-SNAP award progress reports are due two months before the beginning of the next budget period. All annual progress reports except for the Final Progress Report and Type 4s (administrative extensions, SBIR/STTR Fast-Track Phase II)* must be submitted electronically using the eRA Commons RPPR module. Recipients will receive email notification reminders and see a list of progress reports that are due using the eRA Commons 'Status' page.

*These activities continue to use the PHS 398 or PHS 2590 Progress Report as defined by the terms of award.

Multi-Year Funded Awards (MYF): a limited number of grants are MYF which means the project and budget periods are the same and are longer than one year. Progress reports for MYF are submitted using the RPPR and are due on the anniversary date of the award.

Other factors related to a specific grant may add additional requirements. For example, if working with human subjects, a certification of IRB approval must be submitted annually. Likewise if working with research animals, a certification of IACUC approval is required every three years.

Grants management staff review and monitor the submission of these certifications.

### INVENTION REPORTS

Regulations require that recipient organizations report all inventions to the awarding agency (see NIH Grants Policy Statement), as well as include an acknowledgement of federal support in all patents. Recipients are expected to use the Interagency Edison system: http://iEdison.gov.

### FEDERAL FINANCIAL REPORT (FFR)

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient organization. NIH requires all financial expenditure reports to be submitted using the FFR system in the eRA Commons: http://era.nih.gov.

- Both cash transaction data and expenditure data are required to be submitted.
- Cash transactions are reported on a quarterly basis and expenditure data is primarily reported on an annual basis.
- Except for awards under SNAP and awards that require more frequent reporting, annual reports must be submitted for each budget period no later than 90 days after the end of the calendar quarter when the budget period ended.
- If more frequent reporting is required, the frequency and due date will be specified on the NoA.

Other factors related to a specific grant may add additional reporting requirements. These requirements will be specified in the NoA. Grants management staff review and monitor the submission of these requirements.

### FINAL RESEARCH PERFORMANCE PROGRESS REPORT (FINAL RPPR)

A Final RPPR is required for any grant that has ended and any grant that is not to be extended through award of a new competitive segment. The report is due within 120 days of the end of the project period. Generally, the report should be prepared in the same format as the annual RPPR. The Final RPPR requires recipients to report their Project Outcomes. This information will be make publicly available and should include a concise summary of the cumulative outcomes or findings of the project.

## INTERIM RESEARCH PERFORMANCE PROGRESS REPORT (INTERIM RPPR)

If a grant recipient has submitted a Type 2 (Renewal) application on or before the Final RPPR deadline, then submission of an Interim RPPR is required. Like the Final RPPR, recipients are required to report project outcomes including a summary of the cumulative findings of the project at the end of the competitive segment. The Interim RPPR must be submitted via the eRA Commons no later than 120 calendar days from the period of performance end date. If the renewal application is funded, the Interim RPPR will serve as the annual progress report for the final year of the previous competitive segment. If the renewal application is not funded, the Interim RPPR will serve as the Final RPPR.

## PUBLIC ACCESS

Anyone submitting an application or progress report, must comply with the NIH Public Access Policy. To advance science and improve human health, the NIH requires that scientists submit final peer-reviewed journal manuscripts that arise from NIH funds to PubMed Central (http://www.ncbi.nlm.nih.gov/pmc) immediately upon acceptance for publication. Anyone submitting an application or report (including the Research Performance Progress Report) to NIH must include the PubMed Central ID (PMCID) when citing applicable papers that they author or that arise from their NIH-funded research.

NIH Public Access Policy: http://publicaccess.nih.gov

## MYNCBI

Recipients must set up an account in the "My NCBI" system (https://www.ncbi.nlm.nih.gov/account) to manage their bibliographies and publications. The eRA Commons system is linked to the My NCBI system so that recipients can manage all papers in My NCBI. Recipients must link their eRA Commons account to have papers available for selection in the

### Confused about PMCID versus a PMID?

**PubMed Central is an index of full-text papers and the PMCID links to those full-text papers. This is the requirement for NIH applications and reporting. The PMID is a link to an abstract only in PubMed. It is not part of the NIH Public Access Policy and does not meet compliance requirements.**

eRA Commons when completing an RPPR.

Non-competing continuation applications (Type 5) recipients should use My NCBI to report papers.

## PUBLICATIONS IN NON-COMPETING PROGRESS REPORTS

In non-competing continuation awards (Type 5), grantees should use My NCBI to report papers. There are four codes that My NCBI may apply that are acceptable for compliance:

- Complete
- N/A (not applicable)
- PMC Journal in Process
- In process at NIHMS

If the code shows 'Non-compliant' in My NCBI, then it will show as Non-compliant in the RPPR and will not be acceptable. The recipient must correct the publication to a compliant status before the progress report can be successfully submitted to NIH or approved by NIH staff.

## CITING PUBLICATIONS IN COMPETING APPLICATIONS

In competing applications (including Renewal applications – Type 2s) and everywhere else the recipient wishes to cite papers he/she authored or that arose from NIH funding and are subject to the public access policy, (including biosketches):

1. Include the PubMed Central reference number (PMCID) at the end of the citation.
2. Place the Literature Citations in the appropriate location. Locations vary depending on the application type.

For more information about the NIH Public Access Policy including an overview, links to PubMed Central and training resources: https://www.ncbi.nlm.nih.gov/account.

## HUMAN SUBJECTS AND CLINICAL TRIALS REPORTING

If a grant includes human subjects and clinical trials, grant recipients are required to report and update their data in the NIH Human Subjects System (HSS). Links to the HSS are available in the eRA Commons for the Principal Investigators and Signing Officials.

All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov. The NIH has several resources to guide applicant and grant recipients through specific actions and checkpoints related to the NIH policy and federal regulations on registering and submitting results. Reporting requirements are based on NIH policy and federal regulations aimed at increasing the availability of information to the public about clinical trials and their results. It does not affect the design or conduct of clinical trials or define what type of data should be collected.

For more details on the applicable policies, regulations and requirements, please visit the following resources:

Requirements for Registering and Reporting Clinical Trials (this site includes a decision tree tool) https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Policy and Regulations (this site includes links to the corresponding regulations and NIH policy and FAQs) https://grants.nih.gov/policy/clinical-trials/reporting/understanding.htm

## Rebudgeting

The recipient institution is permitted to rebudget between budget categories within the total costs awarded to meet unanticipated requirements, provided the expenditures:

1. Are within the scope of the approved project
2. Enhance and do not impede the successful continuation or completion of the project
3. Are allowable under governing regulations and policies

Some rebudgeting actions may require specific prior approval from the NCI. The NIH Grants Policy Statement and the terms of the award should be consulted regarding current policies on rebudgeting and prior approval authority. The grants management specialist assigned to the project may also be contacted for advice.

## Auditing

In general, recipients who expend $750,000 or more in federal awards are required to have an annual audit performed by a public accountant or a federal, state, or local government audit organization that meets

generally accepted government auditing standards. Organizations expending less than $750,000 during the fiscal year are not required to have an annual audit.

Educational institutions and nonprofit organizations including hospitals are subject to the requirements of the Uniform Guidance at 2 CFR 200.

For-profit organizations, including for-profit hospitals and foreign organizations, can satisfy audit requirements with either of two types according to the 45 CFR 75.501(i).

- A financial related audit as defined in and in accordance with, the Government Auditing Standards, GPO Stock #020-000-00-265-4 the "Yellow Book."
- An audit that meets the requirements of 45 CFR Part 75.

This audit should include review of the internal controls that are maintained to provide reasonable assurance that:

- Financial operations are properly conducted
- Financial reports are presented fairly and accurately
- Applicable laws, regulations, and other grant terms have been complied with
- Resources are managed and used in an economical and efficient manner
- Desired results and objectives are being achieved in an effective manner

The federal government may, at its discretion, review the internal accounting and other control systems during or after NIH support of the grant activity.

## Grant Appeals

HHS permits recipients to appeal certain post-award adverse administrative decisions made by HHS officials (see 45 CFR 16 and appendix to part 16). NIH has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed by the recipient with the Departmental Appeals Board (DAB) (see 42 CFR 50, Subpart D). NIH will assume jurisdiction for the following adverse determinations set forth in 42 CFR 50.404:

- Termination for Cause or Convenience, in whole or in part, of a grant for failure of the recipient to carry out its approved project in accordance with federal statutes, regulations, assurances, an application, a Notice of Award, or terms and conditions of a federal award
- Determination that an expenditure not allowable under the grant has been charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds
- Denial (withholding) of a noncompeting continuation award for failure to comply with the terms of a previous award
- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained)

The formal notice of an adverse determination from the IC will contain a statement of the grantee's appeal rights. In the first level of appeal, the grantee must submit a request for review to the NIH official specified in the notification detailing the nature of the disagreement and providing supporting documents in accordance with the procedures provided in the notification.

If the NIH decision on the appeal is adverse to the recipient or if the request for review is rejected on jurisdictional grounds, the grantee has the option of submitting a request to the Departmental Appeals Board (DAB).

For additional information, see the NIH Grants Policy Statement: http://grants.nih.gov/grants/policy/nihgps/index.htm.

## Transfer of a Grant

NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration of the approved project period (period of performance). A change of recipient that involves the transfer of a grant to or between foreign institutions or international organizations must be approved by the IC's Advisory Council or Board.

- A grant to an individual may not be transferred. However, an

individual fellowship may be transferred to a new sponsoring organization. The transfer process will be the same as for a change of recipient organization

- A change in an individual fellow's department or sponsor within the same organization is not considered a change of recipient organization.
- A successor-in-interest or a name change is not considered a change of recipient.
- A change of recipient organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original recipient's relinquishment of the grant; otherwise, the NIH reserves the right to transfer title to equipment to the new organization
- The NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

The eRA Commons has an online change of institution process that allows the recipient institution's Signing Official to submit an electronic Relinquishing Statement to grants management, and allows the proposed recipient to access the submitted form. The receiving institution must submit an application using the Parent Funding Opportunity Announcement (FOA): http://grants.nih.gov/grants/guide/parent_announcements.htm.

Additional details are available in the eRA Commons Change of Institution User Guide: https://era.nih.gov/commons/user_guide.cfm.

## Grant Closeout

The grant closeout process is initiated as soon as grant support ends. Recipients are required to submit all closeout documentation using the eRA Commons no later than 120 days after the expiration of the project period or after the grant transfers to a new institution. If the recipient is delinquent submitting grant closeout reports, the NCI may initiate a Unilateral Closeout action. This is a serious action for the recipient institution and can impact future funding.

NCI grants management and program directors review closeout documentation to determine that all applicable administrative actions and required work of the recipient have been completed.

In most cases, the recipient is required to submit:

- A final federal financial report (FFR): https://www.whitehouse.gov/sites/default/files/omb/assets/grants_forms/SF-425.pdf
- A final research performance progress report (Final RPPR) or interim research performance progress report (Interim RPPR) if a competing Type 2 renewal application was submitted
- A final invention statement

There must be no discrepancy between the final FFR expenditure data submitted and the FFR cash transactions in the Payment Management System.

If additional information is required after submission of the documents, the NCI will initiate a Final Report Additional Materials (FRAM) request. The PI and the business official will be copied on the notification and a FRAM link will be provided in the eRA Commons to submit the additional information online.

Closeout of a grant does not automatically cancel any requirements for property accountability, record retention, or financial accountability. Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

## Record Retention

### BY THE RECIPIENT

Financial and programmatic records, supporting documents, and all other records that are required by the terms of a grant must be retained by the recipient as follows:

If an audit or other action is in process at the expiration of the 3-year retention period, the records are to be retained until all issues arising from the audit have been resolved by the NCI.

### BY THE NCI

In general, official grant records are retained for six years.

Construction grant records are retained for 20 years.

If a grant is involved in an appeal or litigation, the retention period begins when the case is closed. There is a 3-year retention period for unfunded applications that begins upon notification to the applicant that an award will not be made or upon withdrawal of the grant application.

| | |
|---|---|
| **Awards Not Under SNAP** | Three years from the date the final annual FFR is submitted to the NIH |
| **Awards Under SNAP** | Three years from the date the FFR for the entire competitive segment is submitted to the NIH. This rule applies to all records for the entire competitive segment |
| **Foreign Organizations and Federal Institutions** | Must submit annual expenditure reports for all awards, including those under SNAP, and must retain records for these awards, including those under SNAP, for three years from the date of submission of the annual FFR to the NIH |

# GLOSSARY

# A

**Animals in Research:** Any live, vertebrate animal used for research, research training, biological testing, or related purposes. See PHS Policy on Human Care and use of Laboratory Animals for information and links to legislation and the Office of Laboratory Animal Welfare Regulations.

**Application:** A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

**Appropriation:** Law authorizing Federal Agencies to obligate funds and make payments from the treasury for specified purposes. Appropriations are annual acts and permanent law.

**Assistance:** The award of money, property, services, or anything of value to a recipient in order to support or stimulate a public purpose authorized by Federal statute. Assistance relationships are expressed in less detail than acquisition relationships, and responsibilities for ensuring performance rest largely with the recipient or are shared with the NCI.

**Award:** The provision of funds by NCI, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

# B

**Budget:** A categorical or modular request for funds required to support the proposed activity.

**Budget Period:** The interval of time (usually 12 months) into which the grant project period is divided for funding and reporting purposes.

# C

**Carryover:** As indicated by the Notice of Award (NoA), carryover authority provides grantees permission to carry over funds unobligated at the end of a budget period to the next budget period. For awards under the Streamlined Non-Competing Award Process (SNAP), funds are automatically carried over and are available for expenditure during the entire project period. However, under those awards, the grantee will be required to indicate, as part of its non-competing continuation request, whether its estimated un-obligated balance (including prior year carryover) is expected to be greater than 25 percent of the current

year's total budget as well as provide a dollar estimate of the unobligated balance. The grantee must provide an explanation and indicate plans for expenditure of those unobligated funds. Awards not included in the SNAP population, do not have automatic carryover authority and must submit a written request to NCI in order to receive authorization to use those funds. Obligated, but unliquidated, funds are not considered carryover.

**Catalog of Federal Domestic Assistance (CFDA):** The CFDA is a government-wide compendium of Federal programs and activities that provide assistance or benefits to state and local governments; public, quasi-public, profit, and nonprofit institutions; and specialized groups and individuals. The General Services Administration maintains the Federal assistance information database from which program information is obtained. See the CFDA website at https://www.cfda.gov.

**Close Out:** A procedure to conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy. This includes the Federal Financial Report (FFR), Final Invention Report, and Final Progress Report.

**Competitive Segment:** The initial project period recommended for support (usually 1 to 5 years) or each extension of a project period resulting from the award of a renewal award.

**Contract (Research & Development [R&D]):** An instrument used by the NCI to procure cancer research services and other resources needed by the Federal Government. Contracts are legally binding documents and used when the principal purpose of the transaction is to acquire a specific service or product for the direct benefit of or use by the NCI.

**Contract (under a grant):** A written agreement between a grantee and a third party to acquire routine goods or services.

**Cooperative Agreement:** An award instrument, reflecting an assistance relationship between the NCI and a recipient, in which substantial NCI programmatic involvement is anticipated during performance of the activity.

**Council/Board, Advisory:** National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial

review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

# D

**Direct Costs:** Costs that can be specifically identified with a particular activity or project.

**Department of Health and Human Services (HHS):** Federal Executive Department; component of the U.S. Public Health Service (PHS). The NIH is an agency of the PHS and the NCI is an institute at the NIH.

**Dual Review System:** Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an IC's advisory Board/Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

# E

**Early Stage Investigator (ESI):** A Program Director/Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award.

**Employer Identification Number (EIN):** The EIN number, also known as a Federal tax identification number, identifies a business to the U.S. Internal Revenue Service. The EIN is required on the SF 424 form of a grant application.

**eRA Commons:** NIH's secure web portal where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required: https://commons.era.nih.gov/ commons.

At this site:

- Applicants may access the status of their applications.
- Recipients may access the status of their awards, submit reports and make requests electronically.

**Expedited Board Concurrence and Early Award Initiative:** This NCI initiative focuses on the part of the grant review-and-award cycle in which the NCI has the most influence: award negotiation and issuance. This accounts for 2 months of the 10- to 12-month grant review-and-award process.

# F

**Facilities and Administrative (F&A) Costs:** Costs (previously known as indirect costs) that are incurred by a grantee for common or joint objectives and therefore cannot be identified with a particular project or program.

**Federal Awardee Performance and Integrity Information System (FAPIIS):** The system developed to maintain specific information on the integrity and performance of covered federal agency contractors and grantees. It combines information from the Contractor Performance Assessment Reporting System, as well as proceedings information and suspension/debarment information from the System for Award Management.

**Federal Register:** An official daily publication that provides a uniform system for communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance programs. The Code of Federal Regulations is an annually revised codification of the general and permanent rules published in the Federal Register: https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

**Federal Financial Report (FFR):** The FFR shows the status of awarded funds for the competitive segment as maintained in the official accounting records of the grantee institution.

- SNAP: The FFR is due no later than 90 days after the completion of the project period, excluding awards to Federal institutions
- Non-SNAP: The annual FFR is due 90 days after the end of the calendar quarter in which the budget period ends. The final FFR is due no later than 120 days after the end of the project period. Grantees are required to submit FFRs for continued funding of their grant(s).

**Final Research Performance Progress Report (Final RPPR):** A Final RPPR is required for any grant that has ended and any grant that is not to be extended through award of a new competitive segment. The report is

due within 120 days of the end of the project period.

**Financial Conflict of Interest:** A financial conflict of interest exists when the grantee's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See http://grants.nih.gov/grants/policy/coi/index.htm.

**Foreign Component:** Under a grant to a domestic institution, the performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities meeting this definition include, but are not limited to:

1. the involvement of human subjects or animals;
2. extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities, or;
3. any activity of the grantee having an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

Foreign travel for consultation is not considered a foreign component.

**For-Profit Organization:** An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations also are referred to as "commercial organizations."

## G

**Grant:** financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. Performance responsibility rests primarily with the recipient, and NCI anticipates there will be no substantial Federal involvement or participation in the performance of activities.

**Grants Management Officer (GMO):** The individual designated by an awarding component to be responsible for ensuring that both the granting agency and grantees meet all requirements of laws, regulations, and formally established policies.

**Grants Management Specialist (GMS):** An individual selected by the

Grants Management Officer to serve as the focal point of the awarding component for all business/management activities associated with the negotiation, award, and administration of a grant or cooperative agreement. He/she also interprets grant administration policy and provisions.

**Grants.gov:** The organization designated by the Office of Management and Budget as the single access point for all grant programs offered by 26 Federal grant-making agencies. It provides a single interface for agencies to announce their grant opportunities and for all applicants to find and apply for those opportunities. Registration is required to apply: http://www.grants.gov.

# H

**HHS:** See Department of Health and Human Services

**Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. See the NIH Grants Policy Statement for more: http://grants.nih.gov/grants/policy/nihgps/index.htm.

**Human Subject Assurance:** A document filed by an institution conducting research on human subjects with the HHS Office for Human Research Protections, which formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding: http://www.hhs.gov/ohrp.

# I

**Indirect Costs:** See Facilities and Administrative (F&A) Costs.

**Institute/Center (IC):** The NIH organizational component responsible for a particular grant program or set of activities. The NCI is an IC.

**Institutional Animal Care and Use Committee (IACUC):** A committee set up by an institution to review the institution's program for humane care and use of animals. The IACUC reviews research protocols involving the care and use of animals at the institution and makes recommendations to

the Institutional Official regarding any aspect of the institution's animal program(s), procedures, facilities, or personnel training.

**Institutional Review Board (IRB):** A board or committee set up by a research institution to ensure the protection of the rights and welfare of human research subjects participating in research conducted under its auspices. IRBs make an independent determination to approve, require modifications to, or disapprove research protocols based on whether human subjects are adequately protected, as required by Federal regulations and local institutional policy.

**Integrated Review Group (IRG):** A group of study sections or peer review committees that are arrayed by scientific discipline. Study sections or peer review committees of scientists advise on the scientific and technical merit of research applications submitted for support.

Interim Research Performance Progress Report (Interim RPPR): If a grant recipient has submitted a Type 2 (Renewal) application on or before the Final RPPR deadline, then submission of an Interim RPPR is required.

# J

**Just-In-Time (JIT):** Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award. JIT includes, certification of IRB approval, proof of human subjects education training, certification of IACUC approval, Other Support for key personnel, etc.

# K

**Key Personnel (Senior/Key):** The Principal Investigator (PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for key personnel.

# M

**Modular Grants:** Under modular budget proposals, applicants are instructed to prepare the budget request in direct-cost modules of $25,000 (not including third-party F&A costs) up to a maximum direct-cost level of $250,000. (Budget requests beyond this level follow traditional application instructions.) This process eliminates the need for much budget detail, thereby relieving administrative burdens on both NIH staff and grantee organizations and simplifying cost management for NIH program staff.

**Monitoring:** A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

# N

**New Investigator:** A PD/PI who has not previously competed successfully as a PD/PI for a substantial independent research award is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants.nih.gov/grants/new_investigators/index.htm

**Notice of Award (NoA):** The legally binding document that

- notifies the recipient of the award of a grant;
- contains or references all terms and conditions for the award; and
- documents the obligation of Federal funds.

The award notice is issued electronically and may be accessed through the eRA Commons: http://era.nih.gov/grantees/index.cfm.

**Notice of Special Interest (NOSI):** NIH announcements for specific scientific topics. NOSIs will direct applicants to apply for the funding via a parent or other existing Funding Opportunity Announcement. When completing the application, the institution must reference the NOSI notice number in the Agency Routing Identifier field on the SF424 (R&R) application form so that it will be routed and assigned appropriately.

# P

**Payment Management System (PMS):** The HHS centralized grants payment system operated by the Division of Payment Management, Program Support Center. Most HHS grant recipients (and some other Federal government agencies') recipients receive payments through this system.

**Peer Review (42 CFR Part 52h):** A system for evaluating research applications utilizing reviewers who are the professional peers of the Principal Investigator of the proposed project.

**Principal Investigator (PI):** An individual designated by the recipient organization to direct the project or activity being supported by the grant. He/she is responsible and accountable to recipient organization officials for the proper conduct of the project or program. The organization is, in turn, legally responsible and accountable to the NCI for the performance and financial aspects of the grant-supported activity.

**Prior Approval:** Written approval from NCI's Grants Management Officer required for specified post-award changes to the approved project or budget. Such approval must be obtained prior to undertaking the proposed activity or spending NCI funds.

**Procurement:** The acquisition by purchase, lease, or barter of property or services for the direct benefit or use of the NCI or other Government agency. The procurement instrument most often used is a contract. A contract details the rights, duties, and obligations of each of the parties involved.

**Program Announcement (PA):** A formal statement that describes and gives notice to the grantee community of the existence of an NIH-wide or individual Institute/Center extramural research activity/interest or announces the initiation of a new or modified activity/interest or mechanism of support and invites applications for grant or cooperative agreement support. PAs are published in the NIH Guide to Grants and Contracts: http://grants.nih.gov/grants/guide/index.html. Funds may or may not be set aside for PAs.

**Program Director/Official:** The NCI official responsible for the programmatic, scientific, and/or technical oversight and monitoring of a grant. The program official works closely with grants management staff.

**Project Period:** The total time for which support of a discretionary

project has been programmatically approved. A project period may consist of one or more budget periods. The total project period comprises the initial competitive segment and any extensions.

**PubMed Central (PMC):** PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal papers. These papers are indexed with a PMCID, a series of numbers preceded by 'PMC'. PMC content is publicly accessible and integrated with other databases.
See: http://www.pubmedcentral.nih.gov.

**PubMed Central Reference Number (PMCID):** The reference number assigned to an article or manuscript archived in PubMed Central. The PMCID is the number that must be cited on applications, proposals or reports as part of compliance with the Public Access Policy. See http://publicaccess.nih.gov.

# R

**Recipient:** The organization or individual awarded a grant or cooperative agreement by the NCI that assumes legal, financial, and scientific responsibility and accountability for both the awarded funds and the performance of the grant-supported activity. A recipient organization can be public or private, nonprofit or for-profit, or an educational institution, hospital, corporation, domestic or foreign agency, or other legally accountable entity.

**Request for Application (RFA):** A formal announcement inviting grant or cooperative agreement applications in a well-defined scientific area to support specific program initiatives, indicating the amount of funds set aside for the competition and generally identifying a single application receipt date. RFAs are published in the NIH Guide for Grants and Contracts: http://grants.nih.gov/grants/guide/index.html.

**Research Performance Progress Report (RPPR):** Annual progress report required to document grantee accomplishments and compliance with terms of award. Describe scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year: http://grants.nih.gov/grants/rppr.

**Research Project Grant (RPG):** Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies.

# S

**Scientific Review Group (SRG):** The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. They are a component part of an Integrated Review Group (IRG) that advises on the scientific and technical merit of research applications. Also known as Study Section.

**Scientific Review Officer (SRO):** A Federal scientist who presides over a Scientific Review Group (SRG) and is responsible for coordinating and reporting the review of each application assigned to his/her committee, thereby serving as an intermediary between the applicant institution and the reviewers of the application. The SRO prepares a summary statement for each application reviewed by his/her SRG.

**Small Business:** A business, including its affiliates, that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has no more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 CFR Part 121.

**Stipend:** A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

**Streamlined Noncompeting Award Process (SNAP):** A simplified process for submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP. Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and negotiations, if applicable, and reduces the information the NIH requires to review, approve, and monitor

noncompeting awards. Grantees are required to submit only the RPPR. For awards under SNAP (other than awards to federal institutions), a Federal Financial Report (FFR) is required only at the end of a competitive segment, rather than annually.

## T

**Technical Assistance Review:** An evaluation by NCI grants management staff to assess an institution's business and financial management systems to ensure that applicable regulations and policies are being followed.

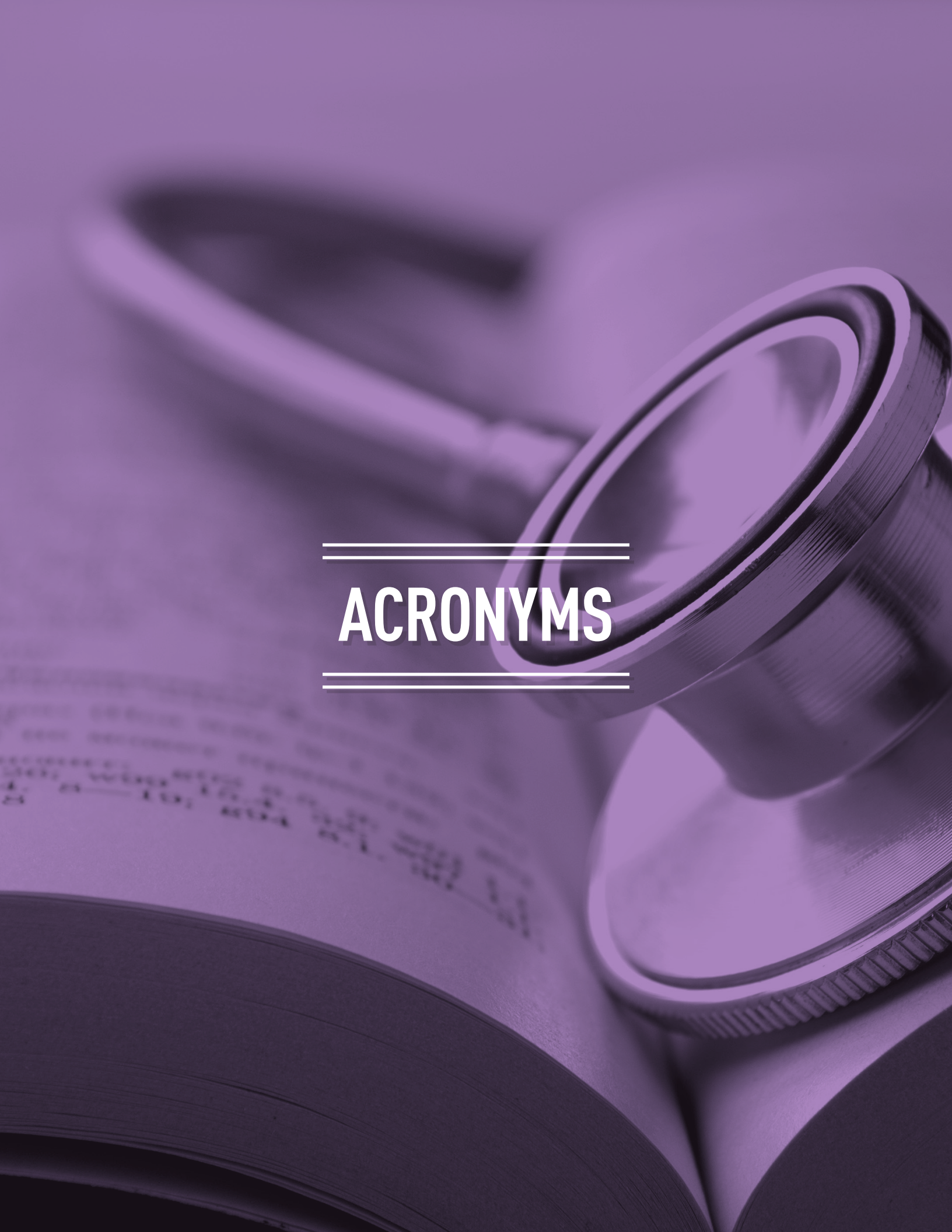
**Terms and Conditions of Award:** All legal requirements imposed on a grant, whether based on statute, regulation, policy, other referenced document, or the grant award document itself. The Notice of Award may include both standard and special provisions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the interests of the Federal Government.

**Total Project Costs:** The total allowable costs (both direct and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NCI grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

**Transfer of Recipient Organization:** Periodically NIH is asked by grantee institutions to accommodate administrative changes for managing grants. In these cases the PI, other researchers and the performance of the research is not changing; however, the administrative oversight and responsibilities for the grant is shifting to a different legal entity. The transfer of a grant requires prior approval by the grants management and program staff assigned to the grant.

## U

**Unobligated Balance:** Funds not used by the completion of a grant's project period. Grantees must report unobligated balances over 25 percent of total costs to the grants management specialist. Grants subject to SNAP may carry over unobligated funds from one budget period to another without prior approval, as stated in the Notice of Award.



# ACRONYMS

| | |
|---|---|
| AO | Administrative Official |
| AOR | Authorized Organizational Representative |
| CCR | Central Contractor Registration |
| CFR | Code of Federal Regulations |
| CGMO | Chief Grants Management Officer |
| CSR | Center for Scientific Review |
| DCB | Division of Cancer Biology, NCI |
| DCCPS | Division of Cancer Control and Population Sciences, NCI |
| DCP | Division of Cancer Prevention, NCI |
| DCTD | Division of Cancer Treatment And Diagnosis, NCI |
| DEA | Division of Extramural Activities, NCI |
| ERA | Electronic Research Administration |
| ESI | Early Stage Investigator |
| F&A | Facilities and Administrative Costs |
| FIS | Final Invention Statement |
| FFR | Federal Financial Report |
| FOA | Funding Opportunity Announcement |
| FPR | Final Progress Report |
| FY | Fiscal Year |
| GMO | Grants Management Officer |
| GMS | Grants Management Specialist |
| HHS | Department of Health and Human Services |
| IC | NIH Institute or Center |
| IRG | Integrated Review Group |
| IRPPR | Interim Research Performance Progress Report |
| JIT | Just In Time |
| NCAB | National Cancer Advisory Board |
| NCI | National Cancer Institute |

| | |
|---|---|
| NIH | National Institutes of Health |
| NoA | Notice of Award |
| OGA | Office of Grants Administration, NCI |
| PA | Program Announcement |
| PAR | Program Announcement Reviewed at the Institute |
| PD | Program Director |
| PHS | Public Health Service |
| PI | Principal Investigator |
| PMS | Payment Management System |
| RFA | Request for Application |
| RPG | Research Project Grant |
| RPPR | Research Performance Progress Report |
| SAM | System For Award Management |
| SBIR | Small Business Innovation Research |
| SNAP | Streamlined Non-Competing Award Process |
| SO | Signing Official |
| SRA | Scientific Review Administrator |
| SRG | Scientific Review Group |
| STTR | Small Business Technology Transfer |

# EXHIBITS

# Research Performance Progress Report (RPPR)

**A. COVER PAGE**

| | |
|---|---|
| **Project Title:** Really Important Advance in Cancer Research | |
| **Grant Number:** 5R01CA123456-02 | **Project/Grant Period:** 01/01/2017 – 12/31/2021 |
| **Reporting Period:** 01/01/2019 – 12/31/2019 | **Requested Budget Period:** 01/01/2020 – 12/31/2020 |
| **Reporting Term Frequency:** Annual | **Date Submitted:** 11/14/2019 |
| **Program Director/Principal Investigator Information:**<br>Someone Deserving, PHD<br><br>**Phone number:**<br>**Email:** | **Recipient Organization:**<br>THE UNIVERSITY<br>RESEARCH & SPONSORED PROJECTS<br>1234 Somewhere St.<br>City, St. ZIP+4<br><br>**DUNS:**<br>**EIN:**<br><br>**RECIPIENT ID: For use by the institution (not required)** |
| **Change of Contact PD/PI:** N/A | |
| **Administrative Official:**<br>Ms. University Contact<br>RESEARCH & SPONSORED PROJECTS<br>1234 Somewhere St.<br>City, St. ZIP+4<br><br>**Phone number:**<br>**Email:** | **Signing Official:**<br>Ms. University Contact<br>RESEARCH & SPONSORED PROJECTS<br>1234 Somewhere St.<br>City, St. ZIP+4<br><br>**Phone number:**<br>**Email:** |
| **Human Subjects:** No | **Vertebrate Animals:** No |
| **hESC:** No | **Inventions/Patents:** No |

## B. ACCOMPLISHMENTS

**B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?**

List the major goals of the project as stated in the approved application or as approved by the agency. If the application lists milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.
Generally, the goals will not change from one reporting period to the next. However, if the awarding agency approved changes to the goals during the reporting period, list the revised goals and objectives. Also explain any significant changes in approach or methods from the agency approved application or plan.

Goals are equivalent to specific aims. Significant changes in objectives and scope require prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2).

The specific aims must be provided in the initial RPPR (i.e., first non-competing type 5 submission). In subsequent RPPRs this section will pre-populate with the aims/goals previously entered and may be amended by answering Yes to question B.1.a.

**B.1.a Have the major goals changed since the initial competing award or previous report?**

Yes or No
Remember that written prior approval from the awarding agency grants official is required for significant changes in the project or its direction. The RPPR is not an appropriate vehicle to request such a change.

**B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?**
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results, including major findings, developments, or conclusions (both positive and negative); and 4) key outcomes or other achievements. Include a discussion of stated goals not met. As the project progresses, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Goals are equivalent to specific aims. In the response, emphasize the significance of the findings to the scientific field. For most NIH awards the response should not exceed 2 pages.

**B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS**

**For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?**
If yes, identify the Revision(s)/Supplements(s) by grant number (e.g., 3R01CA000000-01S1) or title and describe the specific aims and accomplishments for each Revision/Supplement funded during this reporting period. Include any supplements to promote diversity or re-entry, or other similar supplements to support addition of an individual or a discrete project.
The NoA will indicate any reporting requirements. Be advised that the NoA incorporates requirements of the FOA that may also include reporting requirements.

**B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOP HAS THE PROJECT PROVIDED?**
If the research is not intended to provide training and professional development opportunities or there is nothing significant to report during the reporting period, select **Nothing to Report**.
Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project.

For all projects reporting graduate students and/or postdoctoral participants in Section D., describe whether your institution has established Individual Development Plans (IDPs) for those participants. Do not include the actual IDP, instead include information to describe how IDPs are used, if they are used, to help manage the training for those

instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

**B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?**

Reporting the routine dissemination of information (e.g., websites, press releases) is not required. For awards not designed to disseminate information to the public or conduct similar outreach activities, a response is not required, and the grantee should select **Nothing to Report**. A detailed response is only required for awards or award components that are designed to disseminate information to the public or conduct similar outreach activities.

Note that scientific publications and the sharing of research resources will be reported under *Products*.

**B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?**

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives. Remember that significant changes in objectives and scope require prior approval of the agency.

## C. Products

**C.1 PUBLICATIONS**

**Are there publications or manuscripts accepted for publication in a journal or other publication (e.g. book, one-time publication, monograph) during the reporting period resulting directly from this award?**

If there are publications to report; select **Yes.** PD/PIs are required to report all publications that arise from their NIH award in this section. Publications listed in other parts of the RPPR will not be tracked as award products. The tables draw information from the PD/PI's My NCBI account.
Generally, it takes weeks to bring publications into compliance; PD/PIs are advised to do so as soon as possible to ensure their award is renewed in a timely manner

**Publications Reported for this Reporting Period (SAMPLE)**

| | |
|---|---|
| PMC Journal – in process | Deserving S,. Breakthrough: Really Important Cancer Discovery, Clin Cancer Res. 2019 Apr 15. PubMed PMID: 99999999. |

**C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)**

For awards not designed to create or maintain one or more websites, select Nothing to Report. A description is only required for awards designed to create or maintain one or more websites. Limit the response to this reporting period.

**C.3 TECHNOLOGIES OR TECHNIQUES**

Identify technologies or techniques that have resulted from the research activities. Describe the technologies or techniques and how they are being shared. Limit the response to this reporting period.

**C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES**

**Have inventions, patent applications and/or licenses resulted from the award during the reporting period? If yes, has this information been previously provided to the PHS or the official responsible for patent matters at the grantee organization?**

Reporting of inventions through iEdison is strongly encouraged.

**C.5 OTHER PRODUCTS AND RESOURCE SHARING**

**C.5.a Other products**

Describe the product and how it is available to be shared with the research community. Do not repeat information provided above. Limit the response to this reporting period. Examples of other products are: audio or video products; data and research material (e.g., cell lines, DNA probes, animal models); databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

**C.5.b Resource sharing**

PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. For additional information on NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources see http://grants.nih.gov/grants/sharing.htm.

## D. PARTICIPANTS

**D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?**

Provide information for each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation. An individual's eRA Commons user ID may be used to partially populate the information. A Commons ID is required for all individuals with a postdoctoral, graduate or undergraduate role. It is also required for individuals supported by a Reentry or Diversity Supplement.

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SDESERVING | Y | DESERVING, SOMEONE | XXXX | MM/YYYY | BA, PHD | PD/PI | 10 | 0 | 0 | | | NA |
| IASSIST | N | ASSIST, INGRID | XXXX | MM/YYYY | BS/MS | Grad Student (research assistant) | 5 | | | | | NA |

**Glossary of acronyms:**

S/K – Senior/Key
DOB – Date of Birth
Cal – Person Months (Calendar)
Aca – Person Months (Academic)
Sum – Person Months (Summer)
Foreign Org – Foreign Organization Affiliation
SS – Supplement Support
RE – Reentry Supplement
DI – Diversity Supplement
OT – Other
NA – Not Applicable

**D.2 PERSONNEL UPDATES**

**D.2.a Level of Effort**

**Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?**

Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting Yes constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request

**D.2.b New Senior/Key Personnel**

**Are there, or will there be, new senior/key personnel?**

If yes, upload biosketches and other support for all new *senior/key* personnel.

**D.2.c Changes in Other Support**

**Has there been a change in the active other support of senior/key personnel since the last reporting period?**

Select **Yes** if active support has changed for the PD/PI(s) or senior/key personnel. If yes, upload active other support for senior/key personnel whose support has changed and indicate what the change has been. List the award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period.

If a previously active grant has terminated and/or if a previously pending grant is now active, complete Other Support information using the suggested format and instructions found at http://grants.nih.gov/grants/funding/2590/Non-competing_othersupport.docx. Annotate this information so it is clear what has changed from the previous submission.

Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously.

**D.2.d New Other Significant Contributors**

**Are there, or will there be, new other significant contributors?**

Other significant contributors are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. **If yes, upload biosketches for all new other significant contributors.**

**D.2.e Multi-PI (MPI) Leadership Plan**

**Will there be a change in the MPI Leadership Plan for the next budget period?**

Revision of the Leadership Plan during the project period may be accomplished through a joint decision of the PD/PIs and reported in the RPPR. Prior approval of a change in the *MPI Leadership Plan* is not required.

Change in status of PD/PI requires prior approval of the agency, including a request to change from a multiple PD/PI model to a single PD/PI model or a change in the number or makeup of the PD/PIs on a multiple PD/PI award. The RPPR is not the appropriate vehicle to request such a change.

## E. IMPACT

**E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?**

Not applicable for most awards. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) Supplemental Instructions for specific instructions related to Activity Codes.

**E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?**

Describe ways the project made an impact on the aforementioned resources such as facilities, laboratories, establishment of societies, electronic means for accessing resources for scientific communication etc.

If the award or award component(s) is not intended to support physical, institutional, or information resources that form infrastructure, select **Nothing to Report**.

**E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?**

Not applicable for most awards. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) Supplemental Instructions for specific instructions related to Activity Codes.

**E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?**

For domestic awardees provide the dollar amount obligated to first-tier subawards to foreign entities for this reporting period. For foreign awardees provide the dollar amount of the award, excluding all first-tier subawards to U.S. entities, for this reporting period. Dollars provided should reflect total costs.

If more than one foreign country identify the distribution between the foreign countries. Report only cumulative first-tier subaward dollars by country. Do not report foreign travel, purchases, etc., unless part of a first-tier subaward to a foreign country.

## F. Changes

**F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE**

Not applicable for most awards. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) Supplemental Instructions for specific instructions related to Activity Codes.
Recipients are reminded that significant changes in objectives and scope require prior approval of the agency.

**F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM**

Describe only significant challenges that may impede the research (e.g., accrual of patients, hiring of personnel, need for resources or research tools) and emphasize their resolution.

**F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS**

Describe significant deviations, unexpected outcomes, or changes in approved protocols for human subjects, vertebrate animals, biohazards and/or select agents during this reporting period. Remember that significant changes in objectives and scope require prior approval of the agency.

**F.3.a Human Subjects**

If human subject studies are or will be different from the previous submission, include a description and explanation of how the studies differ and provide new or revised Protection of Human Subjects Section and Inclusion of Women, Minorities, and Children sections as described in the competing application instructions. Additional or modified inclusion enrollment reports may also be necessary and should be provided by clicking the Inclusion link in Section G.4.b of the RPPR to make necessary updates in the Inclusion Management System (IMS).

**F.3.b Vertebrate Animals**

If there are or will be significant changes to the uses of vertebrate animals from the previous submission, provide a description of the changes. Examples of changes considered to be significant include, but are not limited to, changing animal species, changing from noninvasive to invasive procedures, new project/performance site(s) where animals will be used, etc. If studies involving live vertebrate animals are planned and were not part of the originally proposed research design, provide a new or revised Vertebrate Animal Section as described in the competing application instructions.

**F.3.c Biohazards**

Describe any changes from the previous submission.

**F.3 d Select Agents**

If the possession, use, or transfer of Select Agents is or will be different from that proposed in the previous submission, including any change in the select agent research location and/or the required level of biocontainment, provide a description and explanation of the differences. If the use of Select Agents was proposed in the previous submission but has not been approved by regulatory authorities, provide an explanation. If studies involving Select Agents are planned and were not part of the originally proposed research design, provide a description of the proposed use, possession, transfer, and research location as described in the competing application instructions.

U.S. Select Agent Registry information: http://www.selectagents.gov/Select%20Agents%20and%20Toxins.html

## G. Special Reporting Requirements

**G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**

Address any special reporting requirements specified in the award terms and conditions in the Notice of Award (NoA) or

Funding Opportunity Announcement (FOA).

**G.2 RESPONSIBLE CONDUCT OF RESEARCH**

Not applicable for most awards. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) Supplemental Instructions for specific instructions related to Activity Codes.

**G.3 MENTOR'S REPORT OR SPONSOR COMMENTS**

Not applicable for most awards. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) Supplemental Instructions for specific instructions related to Activity Codes.

**G.4 HUMAN SUBJECTS**

**G.4.a Does the project involve human subjects?**

If activities involving human subjects are planned at any time during the next budget period at the grantee organization or at any other project/performance site or collaborating institution, select **Yes**. Select Yes even if the project is exempt from the Regulations for the Protection of Human Subjects. Select **No** if activities involving human subjects are not planned at any time during the next budget period.

Policy on research involving human subjects, including definitions, can be found in the NIH Grants Policy Statement or in the competing application instructions. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) for detailed reporting instructions.

**G.4.b Inclusion enrollment data**

If conducting NIH-defined clinical research, reporting the cumulative enrollment of subjects and the distribution by sex/gender, race, and ethnicity is required. See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) for detailed reporting instructions.

**G.4.c ClinicalTrials.gov.**

**Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?**

**If yes, provide the ClinicalTrials.gov identifier, NCT number (e.g., NCT00654321) for those trials.**

**G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT**

**Are there personnel on this project who are or will be newly involved in the design or conduct of human subjects research?**

If yes, provide the name of the individual, the title of the human subjects education program and a one-sentence description of the program.

**G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)**

**Does this project involve human embryonic stem cells?**

Only hESC lines listed as approved in the **NIH Registry** (http://grants.nih.gov/stem_cells/registry/current.htm?sort=rnd) may be used in NIH funded research.

**G.7 VERTEBRATE ANIMALS**

**Does this project involve vertebrate animals?**

**G.8 PROJECT/PERFORMANCE SITES**

**If there are changes to the project/performance site(s) displayed, edit as appropriate.**

See the RPPR Instruction Guide (grants.nih.gov/grants/rppr/) for detailed reporting instructions.

| | | | |
|---|---|---|---|
| **Primary: University of Michigan** | | | 3003 S. STATE. ST.<br>ANN ARBOR, MI 481091274 |

**G.9 FOREIGN COMPONENT**

**Provide the organization name, country, and description of each foreign component.**

**G.10 ESTIMATED UNOBLIGATED BALANCE**

**G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?**

**G.10.b Provide an explanation for unobligated balance.**

**G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will**

**be spent. To determine carryover authorization, see the Notice of Award.**
Recipients not authorized to carryover unobligated balances automatically must submit a prior approval request to the awarding IC.

**G.11 PROGRAM INCOME**
**Is program income anticipated during the next budget period?**
**If yes, provide the amount and source(s).**
Program Income is defined as gross income earned by the grantee organization, a consortium participant, or a contractor under the grant that is directly generated by the grant-supported project or activity or earned as a result of the award.

**G.12 F&A COSTS [applicable to SNAP awards only]**
**Is there a change in performance sites that will affect F&A costs?**
**If yes, provide an explanation.**

## H. Budget [Applicable to non-SNAP awards only]

**H.1 BUDGET FORM**
Select the SF424 Research and Related Budget from the drop down menu and follow the instructions for completing the form in the SF424 Application Guide for NIH (grants.nih.gov/grants/forms.htm)

**H.2 SUBAWARD BUDGET FORM**
For awards with subaward/consortium budgets, select the SF424 Research and Related Budget Subaward Budget and follow the instructions for Preparing Applications with a Subaward/Consortium in the SF424 Application Guide for NIH (grants.nih.gov/grants/forms.htm)

**Grant Number:** 1R01CA123456--01
**FAIN:** R01CA123456

**Principal Investigator(s):**
Someone Deserving, PhD

**Project Title:** Really Important Advance in Cancer Research

Ms. University Contact
Project Representative
The University
Research & Sponsored Projects
1234 Somewhere St.
City, ST ZIP+4

**Award e--mailed to:** institutionawardcontact@institution.edu

**Period Of Performance:**
**Budget Period:** 04/15/2015 – 03/31/2016
**Project Period:** 04/15/2015 – 03/31/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $417,278 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to The University in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the “Terms and Conditions” is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number R01CA123456. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

**SECTION I – AWARD DATA –** 1R01CA123456--01

**Award Calculation (U.S. Dollars)**

| | |
|---|---|
| **Salaries and Wages** | $125,867 |
| **Fringe Benefits** | $22,742 |
| **Personnel Costs (Subtotal)** | $148,609 |
| **Equipment** | $14,580 |
| **Materials & Supplies** | $83,754 |
| **Travel** | $2,835 |
| **Other** | $3,459 |
| **Publication Costs** | $2,430 |
| **Tuition Remission** | $12,137 |
| **Federal Direct Costs** | $267,804 |
| **Federal F&A Costs** | $149,474 |
| **Approved Budget** | $417,278 |
| **Total Amount of Federal Funds Obligated (Federal Share)** | $417,278 |
| **TOTAL FEDERAL AWARD AMOUNT** | $417,278 |

**AMOUNT OF THIS ACTION (FEDERAL SHARE)** $417,278

| SUMMARY TOTALS FOR ALL YEARS | | |
|---|---|---|
| **YR** | **THIS AWARD** | **CUMULATIVE TOTALS** |
| 1 | $417,278 | $417,278 |
| 2 | $414,558 | $414,558 |
| 3 | $410,515 | $410,515 |
| 4 | $405,742 | $405,742 |
| 5 | $404,996 | $404,996 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

**Fiscal Information:**

| | |
|---|---|
| **CFDA Name:** | Cancer Cause and Prevention Research |
| **CFDA Number:** | 93.393 |
| **EIN:** | 9999999999A1 |
| **Document Number:** | RCA123456A |
| **PMS Account Type:** | P (Subaccount) |
| **Fiscal Year:** | 2020 |

| | | | | | | |
|---|---|---|---|---|---|---|
| CA | 8479999 | $417,278 | $414,558 | $410,515 | $405,742 | $404,996 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

**NIH Administrative Data:**
**PCC**: 9KDC / **OC**: 41021 / **Released**: GMO 2019
**Award Processed:** DATE / TIME

**SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01CA123456-01**

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

**SECTION III – TERMS AND CONDITIONS – 1R01CA123456-01**

This award is based on the application submitted to, and as approved by, NIH on the above--titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

**Research and Development (R&D) :** All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non--research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01CA123456. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award;; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110--161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT--OD--08--033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that Page-5 NIH NGA R | Version: 56 - 12/26/2018 2:22:00 PM| Generated on: 11/27/2019 12:06:26 AM reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

**Treatment of Program Income:**
Additional Costs

**SECTION IV – CA Special Terms and Conditions – 1R01CA123456-01A1**

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

**INFORMATION:** In accordance with the National Cancer Institute's (NCI's) Fiscal Year (FY) 2020 funding policies, this award has been issued at 81% of the adjusted requested level*. Support recommended for future years has been adjusted accordingly.

*adjusted requested level: The requested level of support with adjustments made in accordance with the budget narrative in the summary statement and applicable grant policies.

**INFORMATION:** This award, including the budget and the budget period, has been discussed between [Grants Management Specialist] of the National Cancer Institute and [Institution Official] on XX/XX/2019.

**STAFF CONTACTS**
The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

**Grants Management Specialist**: Assigned Specialist First, Last Name
**Email**: gmsemail@nih.gov **Phone**: 240-276-1234 **Fax**: 240-451-1234

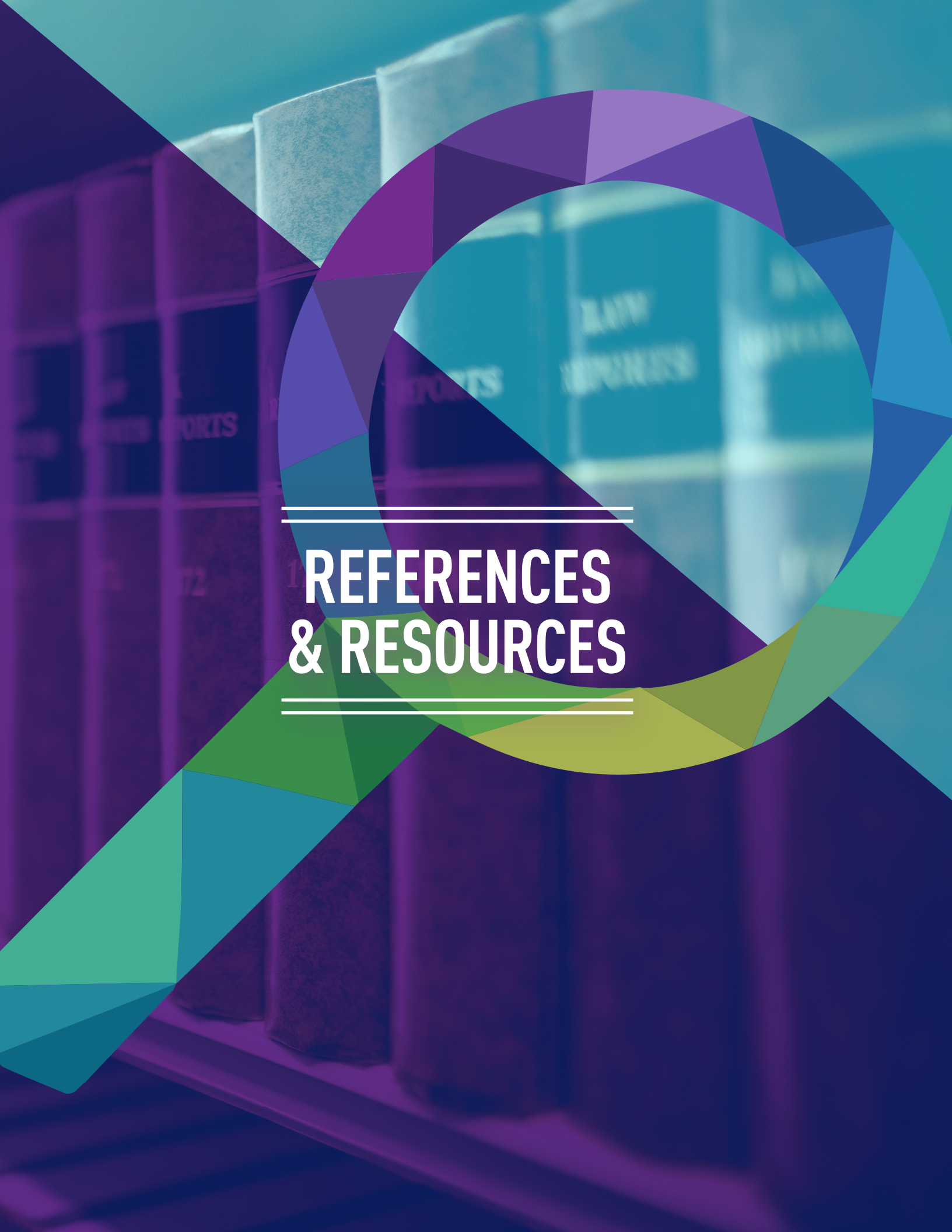
**Program Official:** Subject M. Expert
**Email**: sme@nih.gov **Phone**: 240-276-1234 **Fax**: 240-480-1234

**SPREADSHEET SUMMARY**
**GRANT NUMBER:** 1R01CA123456--01

**INSTITUTION:** THE UNIVERSITY

| Budget | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|
| Salaries and Wages | $125,867 | $125,867 | $125,867 | $125,867 | $125,867 |
| Fringe Benefits | $22,742 | $22,742 | $22,742 | $22,742 | $22,742 |
| Personnel Costs (Subtotal) | $148,609 | $148,609 | $148,609 | $148,609 | $148,609 |
| Equipment | $14,580 | $8,100 | $4,050 | | |
| Materials & Supplies | $83,754 | $83,754 | $83,754 | $83,754 | $83,754 |
| Travel | $2,835 | $2,835 | $2,835 | $2,835 | $2,835 |
| Other | $3,459 | $5,992 | $6,099 | $6,209 | $6,322 |
| Publication Costs | $2,430 | $2,430 | $2,430 | $2,430 | $2,430 |
| Tuition Remission | $12,137 | $11,286 | $10,409 | $9,507 | $8,577 |
| TOTAL FEDERAL DC | $267,804 | $263,006 | $258,186 | $253,344 | $252,527 |
| TOTAL FEDERAL F&A | $149,474 | $151,552 | $152,329 | $152,398 | $152,469 |
| TOTAL COST | $417,278 | $414,558 | $410,515 | $405,742 | $404,996 |

| Facilities and Administrative Costs | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|---|---|---|---|---|---|
| F&A Cost Rate 1 | 62% | 62% | 62% | 62% | 62% |
| F&A Cost Base 1 | $241,087 | $142,112 | $243,727 | $243,837 | $243,950 |
| F&A Costs 1 | $149,474 | $88,109 | $152,329 | $152,398 | $152,469 |



# REFERENCES & RESOURCES

1. **Center for Scientific Review:** Includes application receipt dates as well as review and award schedules: http://public.csr.nih.gov/Pages/default.aspx
2. **NCI Home Page:** http://www.cancer.gov
3. **NCI Office of Grants Administration:** Find grants management contacts for institutions, get answers to questions about the grants lifecycle and on-going administration requirements: http://www.cancer.gov/about-nci/organization/oga.
4. **NCI Division of Extramural Activities (DEA):** Learn the specifics about NCI extramural funding opportunities, advisory boards and groups and the peer review process: http://deainfo.nci.nih.gov.
5. **NCI Publications Locator:** The official resource for free NCI publications, including eBooks, hardcopies, DVDs, etc: https://pubs.cancer.gov/ncipl/home.aspx
6. **NIH electronic Research Administration (eRA) Commons:** Online system to manage all aspects of NIH grants processing and administration: http://era.nih.gov/index.cfm.
7. **NIH Grants & Funding Language:** Find a list of common grants terms and acronyms: http://grants.nih.gov/grants/acronym_list.htm.
8. **NIH Guide for Grants & Contracts:** Official publication for NIH medical and behavioral research grant policies, guidelines, and funding opportunities: http://grants.nih.gov/grants/guide/index.html.
9. **NIH Grants & Funding:** Find everything you need to know about the NIH grants and funding process as well as open funding opportunities and notices: http://grants.nih.gov/grants/oer.htm.
10. **NIH Grants Application Guide:** Find comprehensive instructions, due dates and forms for completing the SF424 (R&R) and Public Health Service (PHS) grant application forms. Should be used in conjunction with the forms and guidance found with the specific Funding Opportunity Announcement: http://grants.nih.gov/grants/how-to-apply-application-guide.htm.
11. **NIH Home Page:** Links to offices within the Office of the Director, as well as to Institute and Center websites; each provides valuable tools and insights into Institute-specific areas of research emphasis: http://www.nih.gov.

12. **NIH Publications:** Provides publications for all Institutes and Centers within NIH: https://nihpublications.od.nih.gov

13. **RePorter:** A reporting database of NIH-funded research projects with a listing of publications patents resulting from that research: https://projectreporter.nih.gov/reporter.cfm



NATIONAL CANCER INSTITUTE

NIH Publication No. 16-1222
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