PROTOCOL
Biomedical Non-Exempt
Berkeley

Protocol #
Date Printed:

Protocol Title:	Biomedical Non-Exempt
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Date Submitted:	Draft
Approval Period:	Draft
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* * * Personnel Information * * *

Enter all UC Berkeley study personnel (if not previously entered) and relevant training information. Please read Personnel Titles and Responsibilities: Roles in eProtocol before completing this section.

Note: The Principal Investigator or Faculty Sponsor, Co-Principal Investigator, Student or Postdoctoral Investigator, Administrative Contact, and Other Contact can EDIT and SUBMIT. Other Personnel can only VIEW the protocol.

Principal Investigator or Faculty Sponsor

Name of Principal Investigator | Degree (e.g., MS/PhD) | Title

Email | Phone | Fax

Department Name | Mailing Address

	Faculty		Postdoc		Grad		Undergrad		Other	

Faculty (with some exceptions), staff, and students engaged in human subjects research must complete either the biomedical or social-behavioral human research course through the online Collaborative Institutional Training Initiative (CITI), depending upon which is most germane to the research. ALL PIs on an NIH award are required to complete either CITI or NIH Training. See Training and Education for more information.

If applicable, please insert date (mm/dd/yy) of completion in appropriate box(es) below:

CITI	NIH	Other Training (title & date completed)

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* * * Vulnerable Subject Checklist * * *

Vulnerable Subject Checklist

Yes	No	
		Children/Minors
		Prisoners
		Pregnant Women
		Fetuses
		Neonates
		Educationally Disadvantaged
		Economically Disadvantaged
		Cognitively Impaired
		Other (i.e., any vulnerable subject population(s) not specified above)

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* * * Study Sites * * *

Study Sites

Select all study sites where data collection via subject interaction will take place:

International

International Site(s) (specify country, region, and township or village)

Local

UC Berkeley
UC Davis
UC Irvine
UC Los Angeles
UC Merced
UC Riverside
UC San Diego
UC San Francisco
UC Santa Barbara
UC Santa Cruz
Lawrence Berkeley National Laboratory
Alameda Unified School District (specify schools below)

Berkeley Unified School District (specify schools below)

Oakland Unified School District (specify schools below)

Other (Specify other Study Sites)

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* * * General Checklist * * *

General Checklist

Yes	No	
		Is the research receiving any federal funding (e.g., NIH, NSF, DOD, etc.)?
		Is another campus relying on UC Berkeley for IRB review by means of the UC System Memorandum of Understanding (MOU)?
		Is another institution relying on UC Berkeley for IRB review by means of an Inter-institutional IRB Authorization Agreement?
		Will subjects be compensated for participation?
		Is this protocol administratively supported by Campus Shared Services Team 9?
		Does this research fall under FDA regulations?
		Any use of human blood, body fluids, tissues, or cells (including cell lines)* by drawing samples, accepting samples already drawn, receiving samples from any source, or in any other way?
		If yes, Lab Location:
		And Biological Use Authorization (BUA) #(s):
		Any use or possible use of controlled substances, either as a study drug or as part of an emergency protocol?
		If yes, provide your controlled substances use authorization (CSUA) number(s). (If you do not have a CSUA #, complete and submit a <a href='https://ehs.berkeley.edu/sites/default/files/project-registration-update-form-controlled-suse.pdf' target='_blank'>Project Registration Form to csuse@berkeley.edu.):
		Will biological specimens be stored for future research projects?
		Will specimens be sent out of UCB as part of a research agreement?
		Will proprietary drug or device testing be done?
		Any use of embryonic stem cells? *NOTE: If research involves embryonic stem cells, see UCB Stem Cell Policy and Committee.
		Any use of medical devices or equipment cleared/approved for marketing?
		Any use of any experimental or investigational devices or equipment (i.e., not cleared/approved for marketing?)
		Any use of commercially available drugs, reagents, or other chemicals administered to subjects (even if drugs themselves are not being studied)?
		Any use of investigational drugs, reagents, or chemicals (i.e., not cleared/approved for marketing)?

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* * * Funding * * *

Funding Checklist

If the research is not funded, check the "Not Funded" box below. If the research is funded, add the funding source to the appropriate table below.

NOTE: Only the Principal Investigator (PI) of the grant or subcontract can add his or her own SPO Funding information in this section. The PI of the grant must also be listed in the Personnel Information section of the protocol in one of the following roles: Principal Investigator or Faculty Sponsor, Student or Postdoctoral Investigator, Co-Principal Investigator, Administrative Contact, or Other Contact. Training Grants can be added by anyone in one of the aforementioned roles. For step-by-step instructions, see Add SPO Funding Quick Guide

Not Funded

SPO - Funding

Funding - Other

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* * * Expedited Paragraphs * * *

Request for Expedited Review

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair, or by one or more experienced reviewers designated by the Chairperson from among the members of the committees.

In order to be eligible for expedited review, ALL aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures included in one or more of the specific categories listed below.

If requesting Expedited Review, select one or more of the applicable paragraph(s) below.
(DO NOT select any paragraph(s) if your protocol does not qualify for expedited review. Protocols that do not qualify for expedited review will be reviewed by the full (convened) Committee.)

1. **Clinical studies of drugs and medical devices only when conditions (a) or (b) are met.**

   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b) Research on medical devices for which

   i) an investigational device exemption application (21 CFR Part 812) is not required; or
   ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

   a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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3. **Prospective collection of biological specimen for research purposes by non-invasive means.**

   Examples:

   a) hair and nail clippings in a non-disfiguring manner;
   b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c) permanent teeth if routine patient care indicates a need for extraction;
   d) excreta and external secretions (including sweat);
   e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f) placenta removed at delivery;
   g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   j) sputum collected after saline mist nebulization.

4. **Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

   Examples:

   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b) weighing or testing sensory acuity;
   c) magnetic resonance imaging;
   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

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6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

8. **Continuing review of research previously approved by the convened IRB as follows:**

   a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b) Where no subjects have been enrolled and no additional risks have been identified; or
   c) Where the remaining research activities are limited to data analysis.

9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.**

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* * * Purpose, Background, Collaborative Research * * *

Old CPHS # (for Protocols approved before eProtocol)

Study Title

Biomedical Non-Exempt

Complete each section. When a question is not applicable, enter "N/A". Do not leave any sections blank.

1. Purpose

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

2. Background

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations if applicable (attach bibliography in Attachments section).

3. Collaborative Research

a) If any non-UCB institutions or individuals are engaged in the research, explain their human research roles and what human subjects training they have/PI has planned to provide.

b) If any non-UCB institutions or individuals are collaborating in the research, complete the table below and attach any relevant IRB approvals in the Attachments section.

4. Qualifications of Study Personnel

a) Explain expertise of Principal Investigator, Student/Postdoc Investigator, Faculty Sponsor (if applicable), any Co-Investigators or other key personnel listed in the application, and how it relates to their specific roles in the study team.

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b) In case of international research, describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research. See Human Subjects Research in an International Setting and <a href='http://cphs.berkeley.edu/international.pdf' target='_blank'>CPHS Guidelines on Research in an International Setting.

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* * * Subject Population * * *

5. Subject Population

a) Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.

b) State the maximum number of subjects planned for the study. This number should account for all subjects to be recruited, including those who may drop out or be found ineligible. Explain how number of subjects needed to answer the research question was determined.

c) If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.

6. Recruitment

a) Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate. See CPHS Guidelines on Recruitment for more information.

b) Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., another UC campus, clinic, school district). Attach these documents in Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.

c) Will anyone who will be recruiting or enrolling human subjects for this research receive compensation for each subject enrolled into this protocol? If yes, please identify the individual(s) and the amount of payment (per subject and total).

7. Screening

a) Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.

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b) **If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: If screening data will be used for research purposes beyond determining eligibility, consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.**

8. Compensation and Costs

a)

Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

Include any provisions for partial payment if subject withdraws before study is complete.

When subjects are required to provide Social Security Number in order to be paid, this data must be collected separately from consent documentation. If applicable, describe security measures that will be used to protect subject confidentiality.

If non-monetary compensation (e.g., course credit, services) will be offered, explain how

b) **Discuss reasoning behind amount/method/terms of compensation, including appropriateness of compensation for the study population and avoiding undue influence to participate.**

c) **Costs to Subjects. If applicable, describe any costs/charges which subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, this should be stated.)**

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* * * Study Procedures, Alternatives to Participation * * *

9. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures. If any interviews, questionnaires, surveys, or focus groups will be conducted for the study, explain and attach one copy each of all study instruments (standard and/or non-standard) in the Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information. If the proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.

b) Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

c) Identify any research procedures that are experimental/investigational. Experimental or investigational procedures are treatments or interventions that do not conform to commonly accepted clinical or research practice as may occur in medical, psychological, or educational settings. Note: if the study only involves standard research or clinical procedures, state "N/A."

d) If a placebo will be used, provide rationale and explain why active control is not appropriate.

e) If any type of deception or incomplete disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. See CPHS Guidelines on Deception and Incomplete Disclosure for more information. Any debriefing materials should be included in the Attachments section.

f) State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).

10. Alternatives to Participation

Describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If the study does not involve treatment/intervention, enter "N/A" here.

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* * * Radiation * * *

11. Ionizing Radiation (e.g. X-ray) and Non-ionizing Radiation (e.g. MRI)

a) Do you intend to use ionizing radioactive materials or ionizing radiation-producing devices in your research (e.g., injectable, oral, x-rays, etc.)? CAUTION: The UCB Radioactive Materials License does not permit human research using radioactive materials or radiation from such materials.

If Yes, provide Radiation Use Authorization (RUA) number(s):

Note: The research may not proceed without an RUA. Please visit:
http://www.ehs.berkeley.edu/how-create-new-radiation-use-authorization-rua

b) Do you intend to use any non-ionizing radiation sources (laser or magnetic sources) in your research?

If Yes, provide Laser Use Authorization (LUA) number(s):

And/or Magnetic Inventory number(s):

Note: The research may not proceed without an LUA or Magnetic Inventory Number. Please visit:
http://ehs.berkeley.edu/laser-safety/how-do-i-register-my-new-laser

c) Describe the source of ionizing radiation or non-ionizing radiation.

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* * * Medical Equipment, Investigational Devices * * *

12. Medical Equipment

If the research involves use of medical equipment, explain whether the equipment is approved for marketing and routinely employed in clinical practice.

13. Investigational Devices

List in the table below all Investigational Devices to be used on subjects

Investigational Devices

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* * * Drugs, Reagents, or Chemicals * * *

14. Drugs, Reagents, or Chemicals

a) List in the table below all investigational drugs, reagents or chemicals to be administered to subjects during this study.

b) List in the table below all commercial drugs, reagents or chemicals to be administered to subjects during this study. In addition to listing study drugs, all commercial drugs (over-the-counter or prescription) that may be used as part of an emergency response plan must be listed in the below table.

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* * * Risks and Discomforts * * *

15. Risks and Discomforts

a) Describe all known risks and discomforts associated with study procedures, whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting the likelihood and degree of potential harm.

b) Discuss measures that will be taken to minimize risks and discomforts to subjects. In terms of minimizing a confidentiality breach, simply refer to section 17 (Confidentiality).

c) If applicable, indicate if a particular study treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

d) If applicable, describe the Data Safety Monitoring Plan (DSMP). NIH may require a DSMP for some projects.

e) Explain how unanticipated negative outcomes/experiences or serious adverse events will be managed. (NOTE: This may apply in social-behavioral as well as biomedical research, e.g., undue stress or anxiety of subject, breach of confidentiality via loss of laptop computer with study data. Provisions should be made and described here if applicable. All commercial drugs (over-the-counter or prescription) that may be used as part of an emergency response plan must be listed in Section 14b (Commercial Drugs, Reagents, Chemicals)).

f) Discuss plans for reporting unanticipated problems involving risks to subjects or others, or serious adverse events, to CPHS. (This applies to all types of research.) See Adverse Event and Unanticipated Problem Reporting.

g) Describe plans for provision of treatment for study-related injuries, and how costs of injury treatment will be covered. If the study involves more than minimal risk, indicate that the researchers are familiar with and will follow University of California policy in this regard, and will use recommended wording on any consent forms (see CPHS Informed Consent Guidelines).

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* * * Benefits, Confidentiality * * *

16. Benefits

Describe any potential benefits to the individual subject, group of subjects, and/or society. If subjects will not benefit directly from study procedures, this should be stated.

NOTE: Do not include compensation/payment of subjects in this section, as remuneration is not considered a "benefit" of participation in research.

17. Confidentiality and Privacy

NOTE: See CPHS Data Security Policy and Guidelines before completing this section.

a) If reviewing or accessing Protected Health Information (PHI) from UC Berkeley's Tang Center, Optometry Clinic, Psychology Clinic, Intercollegiate Athletics, or Human Resources for activities preparatory to research, describe the process and confirm that the health information will not be removed from the "covered entity".

b) What identifiable participant data will you obtain? Note: Audio, photo, and video recordings are generally considered identifiable unless distinguishing features can be successfully masked.

c) If obtaining existing data/specimens, will you have access to identifiers? Please see The Industry Alliance Office website for requirements when receiving existing data/specimens for research.

d) Explain how the confidentiality of subject information will be maintained. Include:

i. Who will have access to study records/specimens? If the study is subject to FDA regulations, include a statement that the FDA might inspect the records of the study.

ii. How the records will be secured (e.g., password-protected computer, encrypted files, locked cabinet). Response should be consistent with CPHS Data Security Policy.

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iii. How long study data will be retained, including signed consent forms. Data retention specifications should adhere to the regulatory requirements applicable to the study (e.g. DHHS, OCR [HIPAA], FDA, etc.).

iv. When audio/video recordings will be transcribed and when they will be destroyed (if ever).

e) Identifiers should be removed from data/specimens as soon as possible following collection, except in cases where the identifiers are embedded (e.g., voices in audio or faces in video recordings). If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored, how it will be protected, who will have access to it, and when it will be destroyed.

f) Describe how identifiable data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit (e.g., prior encryption). If not applicable, enter N/A.

g) Will subjects be asked to give permission for release of identifiable data (e.g., for future studies, publications, presentations, etc.), now or in the future? If so, explain here and include appropriate statements in the consent materials. See Media Records Release Form template for guidance.

h) Explain how subject privacy will be protected (e.g., conducting interviews in a discreet location).

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* * * Potential Financial Conflict of Interest * * *

18. Potential Financial Conflict of Interest

Individuals who have independent roles in projects and who are responsible for the design, analysis, conduct, or reporting of the results of research performed (or to be performed) under a human subjects protocol must disclose whether or not they have a financial interest in or association with a sponsor, a company supplying or manufacturing materials, drugs, or devices being tested under the protocol, or any intellectual property used in the project. This checklist pertains to the entire project team working under the protocol. Any individual who has such an interest and/or potential conflict must comply with University regulations and procedures for disclosure of financial conflict of interest.

See Conflict of Interest Committee Website for more information.

Please answer the following questions:

Does any member of the project team (defined as UCB or non-UCB personnel working under the protocol) with substantive responsibility for the design, conduct, or reporting of activities under the protocol, or any member of their immediate family (defined as spouse, dependent child or registered domestic partner) have any of the following:

1. **Positions of management (e.g., board member, scientific advisor, director, officer, partner, trustee, employee, consultant) at a non-UC entity financing the research to be done under the protocol or at a non-UC entity supplying or manufacturing materials, drugs, or devices being tested under the protocol.**
2. **Equity interest (e.g., stock, stock options, investment, or other ownership) in a non-UC entity financing the research to be done under the protocol or in a non-UC entity supplying or manufacturing materials, drugs or devices being tested under the protocol.**
3. **Intellectual property used in the protocol, such as rights to a pending patent application or issued patent to any invention(s), or license rights or copyright for software that has a direct relationship to the project proposed.**

If the answer to any of the above is Yes, then each individual with any "Yes" response (s) must submit a Human Subjects Financial Conflict of Interest Form and include it in the Attachments section of the protocol.

NOTE: When review by the COI Committee is required, CPHS approval of protocols will be contingent upon the disclosure and resolution of all financial conflicts of interest, as determined by the COI Committee.

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* * * Informed Consent * * *

19. Informed Consent

Add the consent documents and/or waivers needed for this research using the table at the bottom of the page, including any translated versions. For any translated consent, include an affirmation of the translation's accuracy, indicating who is affirming the accuracy (PI, Co-PI, or Student Investigator), in the Consent/Waiver Description or in the Attachment section. Describe the consent process and provide justification for any waivers for each consent document, translation, and/or waiver. The various consent/waiver options are described below.

Note: DO NOT include child assent documents, parent permission documents or waivers here (these are addressed in the next section). The eProtocol system will prevent submission if this section is incomplete. If your study involves only children and no adult subjects, select "Consent Waiver" for the consent type (as this will not require that a document be attached), and put "No Adult Subjects" as the Consent/Waiver Description.

Altered and Unsigned Consent - A consent document that has omitted required information and does not include a place for a participant's signature. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Consent Form - A consent form that has omitted required information. This means that the CPHS is asked to waive one or more required elements of informed consent. For example, if the purpose of the study will not be disclosed to participants in order to avoid bias, this option should be selected because disclosure of the "purpose" is a required element of informed consent. The form must include a signature line and date line for the individual to sign if he or she agrees to participate.

Consent Form - A standard consent document that embodies all of the required information (elements of informed consent) designed to help an individual make an informed decision about whether or not to participate in the research. The form must include a signature line and date line for the individual to sign if he or she agrees to participate. The Consent Form can also be presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a "summary" of the information that is presented to the participant must also be provided for CPHS approval and there must be an impartial witness to the oral presentation. The witness must sign the summary as well as the short form and the participant must sign the summary. The "short form" method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Consent Waiver - No consent will be sought at all. This means that the CPHS is asked to waive the requirement for informed consent. This option is often appropriate for research that involves use of existing data or samples

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Unsigned Consent - A document that embodies all of the required information (elements of informed consent), but does not include a place for a participant to indicate with a signature that he or she agrees to take part in the research. This means that the CPHS is asked to waive the requirement for documented (signed) consent. For example, if consent will be obtained verbally or using a button on the web, this option should be selected.

•Informed Consent Guidelines, Templates and Sample Forms

•Informed Consent Policies and Procedures

Informed Consent

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* * * Child Assent & Parent Permission * * *

20. Child Assent and Parent/Guardian Permission

Add each child assent document, parent/guardian permission document, and/or waiver needed for this research using the table at the bottom of the page, including any translated versions. For any translated consent, include an affirmation of the translation's accuracy, indicating who is affirming the accuracy (PI, Co-PI, or Student Investigator), in the Consent/Waiver Description or in the Attachment section. Describe the consent process and provide justification for any waivers for each consent document, translation, and/or waiver. The various consent/waiver options are described below.

Altered and Unsigned Parent/Guardian Permission Form - A parent permission document that has omitted required information (elements) and does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Parent/Guardian Permission Form - A permission form that has omitted required information (elements). This means that the CPHS is asked to waive one or more required elements of informed consent. However, the form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Assent Document - A form or script of the information that will be conveyed to the child about the study. In general, researchers must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 15 year old is not usually suitable for a 7 year old child).

Assent Waiver - No child assent will be sought at all. This means that CPHS is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefit that is important to the health or well being of the child.

Parent/Guardian Permission Form - A document that embodies all of the required information (elements of informed consent) designed to help the parent/guardian of a child make an informed decision about whether or not to permit the child's participation in the research. The form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Permission Waiver - No parent/guardian permission will be sought at all. This means that the CPHS is asked to waive the requirement for parent/guardian permission. This option, for example, is often appropriate for research designed to study conditions in children or a study population for which parental permission is not a reasonable requirement to protect the children (e.g., neglected or abused children).

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Unsigned Parent/Guardian Permission - A parent permission document that embodies all of the required information (elements of informed consent), but does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that the CPHS is asked to waive the requirement for documented (signed) consent.

•Child Assent and Parent Permission Guidelines, Templates, and Sample Forms

•Policies and Procedures on Child Assent and Parent Permission

Documents and Waivers

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* * * HIPAA * * *

21. Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as a health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes. UC Berkeley's covered entities are the University Health Services (including its health care services on behalf of Intercollegiate Athletics) and the Optometry Clinic. The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without their authorization (i.e., IRB waiver of authorization). For more information, see CPHS Guidelines HIPAA and Human Subjects Research.

a. Does the study involve use of Protected Health Information (PHI) from a "covered entity" outside of UC Berkeley (i.e. another organization or institution)? For more information, see HIPAA and Human Subjects Research.

If Yes, explain what arrangements have been made to comply with the HIPAA requirements of the entity from which the PHI will be obtained:

b. Does the study involve use of a "Limited Data Set" from a covered entity? For more information, see HIPAA and Human Subjects Research Please see The Industry Alliance Office website for limited data set requirements.

If Yes, patient authorization for use of the data set is not required; however, you must have a data use agreement in place with the data holder from which the data will be obtained as required by HIPAA. Contact the Industry Alliance Office for further information at (510) 642-5766.

c. Does the study involve use of Protected Health Information (PHI) from UC Berkeley's University Health Services (including its health care services on behalf of Intercollegiate Athletics) and/or the Optometry Clinic?

If Yes (and a limited data set will not be used), EITHER request/add a Waiver/Alteration of HIPAA Authorization below OR provide a HIPAA Authorization Form in the Attachments section of the protocol.

HIPAA WAIVER/ALTERATION: For each waiver or alteration of the requirement for authorization from the

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patient for use of his or her PHI, provide justification in the table below. For more information, see <a href='http://cphs.berkeley.edu/hipaa/hipaa.html' target=_blank>HIPAA and Human Subjects Research.

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* * * Attachments * * *

22. Attachments

Add appropriate attachments (e.g., advertisements, data collection instruments, IRB approvals from collaborating institutions, etc.) in this section. Attachments MUST be in PDF or Word format. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.

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* * * Assurance * * *

Assurance

As Principal Investigator, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to CPHS requirements, federal regulations, and state statutes for human subject's research.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
3. This protocol covers the human subjects research activities described in the grant proposal(s) supporting this research and any such activities that are not covered have been/will be covered by a CPHS approved protocol.
4. The information provided in this application adheres to all applicable policy requirements, as set forth by the study sponsor(s).
5. The legally effective informed consent of all human subjects or their legally authorized representative will be obtained (unless waived) using only the current, approved consent form(s).
6. If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS will be informed promptly within no more than one week (7 calendar days), and receive a written report within no more than two weeks (14 calendar days), of recognition/ notification of the event.
7. No change in the design, conduct, or key personnel of this research will be implemented without prior CPHS review and approval, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. Changes made to eliminate hazards to subjects will be reported to OPHS/CPHS via the AE/UP reporting process.
8. Applications for continuation review will be submitted in a timely manner prior to the expiration date to allow sufficient time for the renewal process. I understand that if approval expires, all research activity (including data analysis) must cease until I receive notice of re-approval by the CPHS.

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(including data analysis) must cease until I receive notice of re-approval by the CPHS.

9. Participants' complaints or requests for information about the study will be addressed appropriately.

10. I will promptly and completely comply with a CPHS decision to suspend or withdraw its approval for the project.

11. I will submit a study closure form at the conclusion of this project.

I have read and agree to the above assurances.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters