PROTOCOL
Biomedical Exempt
Berkeley

Protocol #
Date Printed:

Protocol Title:

Protocol Type: Biomedical Exempt

Date Submitted: 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

UCB status (select all that apply):

	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 That Apply :

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 paid for participation?		
Does this protocol fit within the scope of the Experimental Social Sciences Laboratory (Xlab) Master Protocol?		
Is this research fall under FDA regulations?		
Is there 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):		
Will biological specimens be stored for future research projects?		
Will specimens be sent out of UC Berkeley as part of a research agreement?		
Will proprietary drug or device testing be done?		
Will any type of deception or incomplete disclosure be used? If yes, submit a non-exempt application.		
Do investigators have a Conflict of Interest (COI)? If yes, submit a non-exempt application.		

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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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* * * Exempt Paragraph(s) * * *

Exempt Paragraphs

There are six categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). If the research is found to be exempt, it need not receive full or subcommittee (expedited) review. However, this determination must be made by OPHS Staff staff and the research may not begin until you have received notification that the research qualified for exemption.

(NOTE: Category 7 does not exist in the federal regulations under 45 CFR 46.101(b); it is an extension of the federal categories as allowed per UCB.s Federalwide Assurance.) For more information and examples of exempt research, see CPHS Guidelines on Exempt Research.

Select one or more of the following exempt categories:

1. EDUCATIONAL PRACTICES: Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:

   i) research on regular and special education instructional strategies; OR

   ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE,ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES,OR OBSERVATION OF PUBLIC BEHAVIOR: Research involving these procedures is exempt, IF:

   i) the information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR

   ii) any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation

   *This exemption does not apply to children except for research involving observation of public behavior when the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior".

3. EDUCATIONAL TESTS, SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR (Research NOT exempt under Category 2): Research involving these procedures is exempt, IF

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i) the subjects are elected or appointed public officials or candidates for public office; OR

ii) federal statute requires confidentiality of identifiable information to be maintained permanently

***In most cases, managers and staff in public agencies are not "public officials".**

4. **EXISTING DATA: Research involving collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, IF:**

i) these sources are publicly available; OR

ii) the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. **RESEARCH AND DEMONSTRATION PROJECTS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF DEPARTMENT OR AGENCY HEADS: This research is exempt IF it is designed to study, evaluate, or otherwise examine:**

i) public benefit or service programs;

ii) procedures for obtaining benefits or services under those programs;OR

iii) possible changes in or alternatives to those programs, OR

iv) changes in methods of payment for benefits under those programs.

6. **TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES: This research is exempt, IF:**

i) wholesome foods without additives are consumed; OR

ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR

iii) a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA

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7. RESEARCH THAT INVOLVES NO GREATER THAN MINIMAL RISK TO SUBJECTS, BUT DOES NOT CONFORM TO A SPECIFIC EXEMPT CATEGORY UNDER 45 CFR 46.101(b) (exempt categories 1 through 6).

Category 7 minimal-risk exempt research activities that may include (but are not limited to) non-physically invasive interventions or performance of tasks such as:

Reading/writing/drawing tasks. Physical activities such as walking, sitting, or manipulating an object. Computer tasks and/or doing Internet searches. Talking and/or listening to words, then making selections, or “think-aloud” exercises. Viewing media. Role-playing. Asking subjects to complete a specific physical or mental action (“imagine”). Passive monitoring of space (environment) with sensors. Playing a game. Height/weight measurements.

Such research is NOT exempt if it involves any of these exclusions.

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* * * Purpose,Study Procedures, Collaborative Research and Background * * *

Title

Biomedical Exempt Test 1

Complete Sections 1 - 10. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose of the study

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

2. Background

a) Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations (with attached bibliography) if applicable.

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. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures and who will conduct each (e.g., how participants are identified, the consent process, interventions/interactions with subjects, data collection), 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

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Attachments Check List for Exempt Applications for more information. Indicate frequency and duration of visits/sessions, as well as total time commitment for participants in the study and an estimated time frame for when the study will be completed. If the proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.

b) State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

c) 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.

d) If the proposed research involves use of existing data/specimens, check all that apply:

i) coded private information or specimens, and the investigator will not have access to the key.

ii) from publicly available sources.

iii) recorded by the investigator in such a manner that subjects cannot be identified OR any link to identifying information has been destroyed.

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* * * Subject Population * * *

5. Subject Population

a) Describe proposed subject population, including criteria for study inclusion and exclusion (e.g., age, health status, language, gender, race, ethnicity). State total (maximum) number of subjects planned for the study and how many must be recruited to obtain this sample size.

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* * * Risks/Discomforts * * *

6. 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 probability and magnitude of potential harm.

b) If conducting educational tests, survey procedures, or observation of public behavior, AND linking to subjects' identifying information, explain why inadvertent release of the data would not have detrimental consequences (i.e. place subjects at risk of civil or criminal liability, or cause damage to their financial standing, employability or reputation).

c) 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 (e.g., differences with U.S. culture). See CPHS Guidelines on Research in an International Setting.

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* * * Confidentiality * * *

7. Confidentiality

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

a) Will data be collected anonymously (i.e., no identifying information from subjects will be collected/ recorded that can be linked to the study data)? If no, please list all identifiable and/or coded data elements to be collected. Data is not anonymous if there is a code linking it to personally identifiable information. Also, audio and video recordings are generally not considered anonymous unless distinguishing features can be successfully masked.

(b). Explain how data, audiotapes, videotapes and photographs, etc. will be secured (e.g., password-protected computer, encrypted files, locked cabinet)stored and who will have access to them. Indicate at what point they will be transcribed and/or destroyed (if ever).

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* * * HIPAA Background * * *

8. 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 Tang Health Center, the Human Resources Health Plan, Athletics and Recreational Sports, and 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 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 (whether a HIPAA Authorization form is being obtained, or a Waiver of HIPAA Authorization was granted) and either submit the HIPAA Authorization or the data holder's approved Waiver of HIPAA Authorization in the Attachments section:

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 entity from which the data will be obtained as required by HIPAA. Attach a copy of the agreement in the Attachments section.

c. Does the study involve use of Protected Health Information (PHI) from UC Berkeley's Tang Health Center, the Human Resources Health Plan, Athletics and Recreational Sports, and/or the Optometry Clinic?

If Yes (and a limited data set will not be used), the study WILL NOT qualify for exempt status and this application form should be deleted and an application for expedited review should be completed in its place.

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* * * Attachments * * *

9. Attachments

Add appropriate attachments (e.g. survey instrument(s), interview guide(s), reference list, other IRB approvals, etc.) in this section. Attachments must be in PDF format. Please see eProtocol Attachments Check List for 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 this 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) (if applicable) supporting this research and any such activities that are not covered have been/will be covered by a CPHS approved protocol.
4. No change in the design, conduct, funding, or personnel of this research will be implemented without prior CPHS review and approval.
5. Participants' complaints or requests for information about the study will be addressed appropriately.
6. I will follow all relevant University of California system and UC Berkeley policies.
7. Should there be any changes that render this study no longer eligible for exempt review, I will submit a new non-exempt application for CPHS review and approval.

I have read and agree to the above assurances.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters