PROTOCOL
Soc-Behav-Ed Exempt
Berkeley

Protocol #

Protocol Title:
Protocol Type: Soc-Behav-Ed Exempt
Date Submitted: Draft
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* * * Personnel Information * * *

Enter all 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 | Fax

Email | Phone

Department Name | Mailing Address

UCB status (select all that apply):

	Faculty		Postdoc		Grad		Undergrad		Other	

ALL PIs and KEY PERSONNEL on an NIH award are required to complete NIH Training or an accepted equivalent. ALL STUDENTS engaged in human subjects research are required to complete CITI 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?

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* * * Funding * * *

Funding Checklist

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 and the research may not begin until you have received notification that the research qualified for exemption.

For more information and examples of exempt research, see CPHS Guidelines on Exempt Research.

Select one or more of the following paragraphs:

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

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OBSERVATION OF PUBLIC BEHAVIOR (Research NOT exempt under Category 2): Research involving these procedures is exempt, IF

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

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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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* * * Purpose,Study Procedures and Background * * *

Title

x

Complete Sections 1 - 9. 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 here.

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.

Non-UCB institutions

4. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., interventions/interactions with subjects, data collection, photographing, audio- and/or videotaping), including follow-up procedures. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

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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) 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

Describe proposed subject population, including criteria for study inclusion and exclusion (e.g., age, health status, language, gender, race, ethnicity).

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* * * Risks * * *

6. Risks and Discomforts

a) Describe all known risks and discomforts associated with study procedures, whether physical, psychological, 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, interview 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, and training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research. See CPHS Guidelines on Research in an International Setting.

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* * * Procedures to Maintain Confidentiality * * *

7. Confidentiality

NOTE: See CPHS Data Security Policy 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)? 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) If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?

c) Explain how data, audiotapes, videotapes and photographs, etc. will be 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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* * * Attachments * * *

8. 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 formt.

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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. No change in the design, conduct, key personnel of this research will be implemented without prior CPHS/OPHS review and approval.
5. Participants' complaints or requests for information about the study will be addressed appropriately.
6. I will submit a study closure form at the conclusion of this project.

I have read and agree to the above assurances.
