

ENGAGEMENT IN HUMAN SUBJECTS RESEARCH

This guidance document is intended facilitate determinations of whether or not UC Berkeley is engaged in human subjects research. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

Table of Contents:

- A. [Introduction](#)
- B. [Definitions](#)
- C. [Determining Engagement](#)
- D. [Engagement Scenarios](#)
- E. [U.S. Department of Education Engagement Guidelines](#)
- F. [CPHS/OPHS Review](#)
- G. [Additional Information](#)

A. Introduction

This guidance document applies to human subjects research that is conducted by employees or agents of University of California, Berkeley (UCB). UCB is considered “engaged” whenever employees or agents of UCB are conducting human subjects research activities.

Review by an institutional review board (IRB) is required whenever the institution is engaged in human subjects research. Researchers may either seek review by the Committee for Protection of Human Subjects (CPHS)/Office for Protection of Human Subjects (OPHS) or request that UCB rely on the review of another institution’s IRB.

B. Definitions

1. **Engagement:** The Office for Human Research Protections (OHRP) considers an institution “engaged” in non-exempt human subjects research¹ when its employees or agents, for the purposes of a research project, obtain:
 - a. Data about the subjects of the research through intervention or interaction with them;
 - b. Identifiable private information about the subjects of the research; or
 - c. The informed consent of human subjects.

CPHS and OPHS base their determinations of *engagement* on the [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#). CPHS/OPHS considers UCB *engaged* in human subjects research when a UCB researcher initiates a human subjects research study or UCB receives a grant, contract, or cooperative agreement from a funding agency (e.g., National Institutes of Health, National Science Foundation, Department of Defense) to conduct human subjects research. UCB will still be considered *engaged* in human subjects research whenever a UCB researcher initiates a human subjects research study, even if all activities involving human subjects are carried out by another entity (e.g., contractors, enumerators, collaborators) and that entity only provides de-identified data to the UCB researchers.

¹ Though OHRP guidelines refer specifically to non-exempt research, CPHS also applies them to exempt research.

2. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
3. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:
 - a) Obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - b) Obtains, uses, studies, analyzes, or generates identifiable *private information* or identifiable biospecimens.

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) to constitute research involving human subjects.

4. **Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions).
5. **Interaction** includes communication or interpersonal contact between investigator and subject.
6. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., education records or medical records).
7. **Identifiable information** refers to information that:
 - a. Can be linked to specific individuals;
 - b. Can allow others to ascertain the identities of individuals based on a combination of the information/characteristics; or
 - c. Meets the definition of a coded data set.

See [FAQ "What constitutes 'identifiable information'?"](#) for further information.

8. **Coded** means that:
 - a. Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the *code*); and
 - b. A *key* to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
9. **De-identified information** refers to information or data sets that consist of no identifiable information and no link/information that would allow others to ascertain the identities of individuals. (Coded information is considered identifiable.)
10. **Institution** refers to any public or private entity or agency.

- 11. **Employees or agents** refers to individuals who: (a) act on behalf of the institution; (b) exercise institutional authority or responsibility; or (c) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.
- 12. **Initiates**, in the context of research engagement, refers to the researcher/institution responsible for setting the human subjects research project in motion. Another way to think of this is the institution with the original research idea, without whom the research would not occur.

C. Determining Engagement

Researchers should first determine whether or not a given project is “research” that involves “human subjects.” If the project constitutes “human subjects research,” researchers should then determine whether or not UC Berkeley is considered engaged in human subjects research.

Part D of this document outlines scenarios that would generally result in UCB being engaged or not engaged. If the research adheres to one or more “engaged” scenarios, then UCB is considered engaged in human subjects research and researchers are responsible for seeking necessary IRB review. This remains true even if parts of the research resemble one or more of the “not engaged” scenarios.

For advice or to request an engagement determination by OPHS, researchers should contact OPHS at ophs@berkeley.edu. UCB faculty who are serving as a consultant with a non-UCB organization should contact OPHS for consultation.

D. Engagement Scenarios

	Engaged	Not Engaged
Use of UCB Resources	(a) An employee or agent of UCB uses UCB resources or facilities (e.g., computers or lab) to conduct human subjects research as an affiliate of UCB. (b) Non-UCB researchers recruit subjects and/or conduct research within UCB dormitories.	(a) Non-UCB researchers are recruiting and/or conducting research on the UCB campus but not within UCB dormitories. The non-UCB researcher is responsible for abiding by the policies of his/her home institution’s IRB and for obtaining appropriate permission to recruit from UCB groups and organizations. (b) An employee or agent of UCB rents UCB facilities/lab space to conduct research for a non-UCB entity (e.g. a private company) and will not use UCB as their affiliation for any final publications/presentations related to the research.
Student Research	A UCB student is proposing to conduct human subjects research as a student of UCB or will be using human subjects research data for a thesis or dissertation.	A UCB student is conducting human subjects research as an agent or affiliate of another institution (e.g., they are an employee or volunteer) and will not use the research/data for their thesis/dissertation nor will they note UCB as their affiliation for any final publications or presentations related to the research.
Visiting Scholar Research	A visiting scholar is proposing to conduct human subjects research as an affiliate of UCB. The visiting scholar must have a UCB Faculty Sponsor as the PI on the research protocol.	A visiting scholar is proposing to conduct human subjects research as an affiliate of their home institution. No UCB investigators are collaborating on the project. The visiting scholar

		must obtain IRB/ethics review from their home institution.
Funding	UCB is the prime-awardee on a grant funding human subjects research. UCB is still considered engaged even when all study activities are conducted by non-UCB researchers (e.g., contractors, enumerators, collaborators).	
Research Design	Employees or agents of UCB initiated the human subjects research or will be leading the human subjects research.	UCB employees or agents are involved in the design, in a consulting role, but did not initiate the human subjects research and will not otherwise be conducting any human subject research activities (e.g., recruitment, obtaining consent, data collection, interventions/interactions, and data analysis).
Recruitment	Employees or agents of UCB are representing the research/researchers (e.g., UCB personnel are actively identifying/approaching potential subjects and encouraging them to participate in a research project).	UCB employees or agents are limited to: (1) informing prospective subjects about the availability of the research; (2) providing prospective subjects with information about the research (e.g., passively distributing recruitment materials); <u>or</u> (3) seeking subject permission to be contacted by a researcher for recruitment.
Research Procedures	An employee or agent of UCB: (1) intervenes for research purposes with any human subject of the research by performing invasive/noninvasive procedures or manipulates the environment; and/or (2) interacts, for research purposes, with any human subject of the research (e.g., performs protocol dictated communication or interpersonal contact, obtains consent, and conducts research interviews/questionnaires/surveys). Online procedures are considered an “interaction.”	UCB employees or agents perform commercial or other services, given that: (1) the services performed do not merit professional recognition or publication privileges; (2) the services performed are typically performed by UCB for non-research purposes; <u>and</u> (3) the employees or agents do not administer any study intervention being tested or evaluated under the protocol.
Data Analysis	UCB employees or agents will access, obtain, use, or analyze private identifiable information/samples for research purposes (e.g., identifiable information/samples, coded research data/samples, observations or recordings of private behavior). See also: Secondary Analysis of Existing Data	(1) UCB employees or agents are only obtaining, accessing, or analyzing de-identified research data; (2) UCB employees or agents are obtaining, accessing, or analyzing coded research data from another institution and have entered into a data use agreement that prohibits any identifiers from being released to the UCB researchers; (3) The role of UCB employees or agents are limited to releasing data/samples to other individuals/entities and are not otherwise involved in the research (i.e., not involved in the

		design, data analysis, and will not receive professional recognition nor publication privileges); <u>or</u> (4) UCB employees or agents access or utilize individually identifiable private information only while visiting a non-UCB institution that is engaged in the research, provided UCB research activities are overseen by the IRB of the institution that is engaged in the research.
--	--	--

E. U.S. Department of Education Engagement Guidelines

The [U.S. Department of Education \(ED\)](#) has additional requirements and engagement guidelines for ED-funded non-exempt human subjects research.

ED considers an institution “engaged” in non-exempt human subjects research when its employees or agents, for the purposes of a research project:

- a. intervene or interact with living individuals; or
- b. obtain individually identifiable private information.

ED regulations at 34 CFR 97.103(a) require that each institution engaged in human subjects research provide an assurance to comply with the regulations and obtain IRB approval, unless the research is exempt under 34 CFR 97.101(b). The assurance can be the [Federal Wide Assurance](#) on file with the Department of Health and Human Services (HHS).

Engagement scenarios specific to ED-funded, non-exempt research (note that, depending on the scenario, “institution” may refer to UC Berkeley or to another institution where research is being conducted, such as an elementary school or other organization):

	Engaged	Not Engaged
Institutional Resources		An institution permits use of its facilities for intervention or interaction with subjects by research investigators (e.g., a school permits researchers to test students whose parents have provided written permission for their participation).
Recruitment/ Informed Consent	An institution's employees or agents act as authoritative representatives of the researchers and/or obtain the informed consent of research subjects on behalf of the researchers.	An institution's employees or agents a) inform prospective subjects about the availability of research; b) provide prospective subjects with written information about research (but do not obtain subjects' consent or act as authoritative representatives of the researchers); c) provide prospective subjects with information about contacting researchers for information or enrollment; d) obtain and document prospective subjects' permission for investigators to contact them (e.g.,

		a school psychologist provides investigators with contact information about potential subjects after receiving explicit permission from each potential subject/parent).
Research Procedures	An institution (e.g., an elementary school) that is not the grantee under an ED award, collaborates with the grantee by performing research activities involving human subjects (e.g., the school staff administer surveys to fourth graders as part of the research initiative). The school must have an Assurance and IRB approval even though it is not the grantee.	An institution receives "coded" data from another institution, provided that: a) the institution whose employees or agents release the coded data provides a statement, satisfactory to ED, that it will not release the identifying codes to the research institution and that the data are not otherwise identifiable; and b) the institution that receives the coded data provides a written signed statement, satisfactory to ED, that it will not attempt to identify the individuals.
Secondary Data Analysis	An institution's employees or agents utilize identifiable private information in circumstances where the institution originally obtained the data for purposes other than the research. Note: FERPA does not allow schools to disclose information from student records without parental or student consent if the disclosure does not meet one of several exceptions outlined in the FERPA regulations.	An institution's employees or agents release identifiable private information to researchers. The institution discloses the information in compliance with applicable policies and laws, including the Family Educational Rights and Privacy Act (FERPA) . The institution does not need an Assurance or IRB approval. Note: FERPA, 34 CFR Part 99, allows schools to disclose "student directory information" without consent as long as the school has informed the parents about the directory information and given them the opportunity to opt out of having directory information disclosed.

F. CPHS/OPHS Review

In collaborative research, multiple institutions may be engaged in the same human subjects research project. If UCB is engaged in only a part of a collaborative research project (see engagement scenarios in Parts D and E) then researchers must ensure that those part(s) of the research are submitted to CPHS/OPHS for review. If deemed necessary, CPHS/OPHS may require that the researchers submit the entire research study. In place of seeking review with CPHS/OPHS, researchers may request that UCB rely on a collaborating institution's IRB review.

For collaborative research within the University of California (UC) System, researchers should refer to: [UC IRB Reliance Registry for studies under the UC MOU](#)

For collaborative research outside of the UC System, researchers should refer to: [Relying on Another IRB for Review](#)

G. Additional Information

[OHRP Guidance on Engagement of Institutions in Human Subjects Research](#)

[U.S. Department of Education Guidance on “Engagement” of Institutions in Research](#)

[Reliance Agreements for Non-UC Collaborations](#)

[Relying on Another IRB for Review](#)

[Secondary Analysis of Existing Data](#)

[UC IRB Reliance Registry for studies under the UC MOU](#)