

Policy Number: 2

Title: Activities Subject to UCLA IRB/OPRS Jurisdiction

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I. Introduction

All research involving human subjects that is conducted by UCLA faculty, staff, or students, or that involves UCLA property, facility or funding, must be reviewed and approved by the UCLA IRB, or certified exempt from IRB review by the UCLA OPRS. UCLA IRB/OPRS jurisdiction is specified in Section III(B) below. This applies whether or not research is funded, and regardless of funding source. This also includes all other activities which may even in part involve human subjects research.

In addition, all research conducted by **non-UCLA** researchers **which proposes to recruit UCLA students as subjects** must be submitted to the UCLA IRB/OPRS for a determination of whether proposed research involving human subjects falls within the UCLA IRB/OPRS's jurisdiction and requires IRB review and approval or Certification of Exemption from IRB review.

Investigators must obtain UCLA IRB approval or certification of exemption prior to engaging in interventions or interactions with human subjects in research, including recruitment, and collection of data about or samples from human subjects.

Specific determinations as to the definition of "research" or "human subjects", and their implications for the jurisdiction of the IRB under federal regulations and UCLA policy, are made solely by the UCLA IRB/OPRS. Please refer to [OPRS/IRB Policy 1: Human Subjects Research Overview](#), and [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for additional details.

II. Definitions

- A. **Research** is defined by 45 CFR 46.102(d) as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- B. **Human subject** is defined by 45 CFR 46.102(f) as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data

through intervention or interaction with the individual, or (2) identifiable private information.

1. **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
2. **Interaction** includes communication or interpersonal contact between investigator (or his/her research staff) and subject (or the subject's identifiable private information).
3. **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 (for example, a medical record). 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) in order for obtaining the information to constitute research involving human subjects. Identifiable private information obtained from a primary participant about a third party may constitute research involving human subjects.

C. **Human subject** is defined by the FDA in 21 CFR 50.3(g) and 56.102 (e) as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. For device research, a subject is also an individual on whose specimen a device is used (21 CFR 812.3(p)).

D. **Clinical Investigation** is defined by the FDA in 21 CFR 50.3(c) and 56.102(c) as any experiment that involves a test article and one or more human subjects and that is subject to FDA regulations.

1. **Test article:** is defined by the FDA in 21 CFR 50.3(j) and 56.102(l) as any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

E. **Human Subjects Research:** Any research that involves humans as defined in 45 CFR 46.102(f) or any clinical investigation that involves humans as defined by the FDA.

III. Activities That Require UCLA IRB/OPRS Review

A. The IRB is established to review biomedical and behavioral research involving human subjects regardless of sponsorship and location of the study. All human subjects research, and all other activities which in part involve human subjects research, require UCLA IRB

review and approval or UCLA OPRS Certification of Exemption from IRB review as outlined in Section III(B) below.

1. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research, or the research has been certified exempt from IRB review.
 2. As detailed in [OPRS/IRB Policy 3: Human Subjects Research Determinations](#), it is the UCLA IRB/OPRS's responsibility to determine what activities constitute human subjects research and require IRB review and approval or Certification of Exemption from IRB review.
- B. UCLA's Assurance with the Federal government defines its jurisdiction over the review of human subjects research. Regardless of sponsorship, UCLA IRB review and approval or UCLA OPRS Certification of Exemption from UCLA IRB review is required for all human subjects research if one or more of the following apply:¹
1. the conduct or recruitment of the research involves UCLA resources (property, facility or funding, including extramural funds administered by UCLA); or
 2. the research is conducted by or under the direction of any employee, student or agent of UCLA in connection with his or her institutional responsibilities; or
 3. the research is conducted by or under the direction of any employee, student or agent of UCLA using any property or facility of UCLA; or
 4. the research involves the use of UCLA's non-public information to identify or contact human research subjects or prospective subjects.
- C. All research conducted by **non-UCLA** researchers **who propose to recruit UCLA students as subjects** must be submitted to the UCLA IRB/OPRS for a determination of whether proposed research involving human subjects falls within the UCLA IRB/OPRS's jurisdiction and requires IRB review and approval or Certification of Exemption from IRB review. Please refer to [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for additional details. This includes non-UCLA investigators who use publicly available resources, such as email addresses in the UCLA directory, standing on Bruin Walk conducting surveys, etc., to recruit UCLA students as subjects.
- D. The use of existing private identifiable data about living individuals, such as medical or academic records, for research purposes may constitute human subjects research as defined by this policy and the federal regulations. If a UCLA Investigator intends to

¹ UCLA's "engagement" in a research project is further determined by January 1999 guidance from OHRP, *Engagement of Institutions in Research*, available at <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>. In the case of FDA-regulated research, UCLA's "engagement" is also further determined by guidance from FDA, *IRB Information Sheets: Use of Investigational Products When Subjects Enter a Second Institution*, available at <http://www.fda.gov/oc/ohrt/irbs/investigational.html>.

publish or disseminate data that were collected for non-research purposes and derived from private identifiable information about living individuals in academic/professional media or at academic/professional meetings or settings, UCLA IRB review and approval, Certification of Exemption from UCLA IRB review, or a determination that the activity is not human subjects research is required prior to accessing the data for research purposes.

1. Researchers should consider, “*Would the project be conducted as proposed if I knew that I would never receive any form of academic recognition for the project, including publication of results in a medical journal or presentation of the project at an academic meeting?*” If the lack of academic recognition would affect the conduct of the project, then research intent is a primary motive for the activity, and UCLA IRB review and approval or Certification of Exemption from UCLA IRB review will be required.
- E. If a UCLA Investigator begins a non-research project and later finds that the private identifiable data about living individuals gathered could develop or contribute to generalizable knowledge, the Investigator must submit a proposal to the UCLA IRB/OPRS for review and approval or certification of exemption from IRB review for the analysis of the data for research purposes prior to publication or presentation of the data (e.g., journal article, poster session, public speech or presentation, or project report). UCLA Investigators who determine *during the conduct of a non-research project* that non-research project data derived from private identifiable information about living individuals could develop or contribute to generalizable knowledge must seek IRB approval at that time, *prior* to the collection or analysis of *additional* data which s/he intends to analyze for research purposes.
- F. UCLA student-conducted research which includes activities that meet the definition of research with human subjects requires IRB review and approval or Certification of Exemption from IRB review. Please refer to [OPRS/IRB Policy 4: Research Conducted by UCLA Students](#) for more information.
- G. Pilot studies that meet the definition of human subjects research, regardless of the number of subjects enrolled or the duration of the study, require UCLA IRB review and approval or Certification of Exemption from IRB review.
- H. UCLA IRB review and approval or Certification of Exemption from IRB review is required when (1) a UCLA investigator collects private identifiable data about living individuals about a series of standard procedures or treatments for dissemination or generalization; (2) a patient's care or assignment to intervention is altered for research purposes in any way; (3) a diagnostic procedure is added for research purposes to a standard treatment; or (4) an investigator conducts a systematic investigation involving innovative procedures or treatments (e.g., if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to standard treatment).

Please refer to [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for details of the UCLA IRB/OPRS's responsibility for determining what activities constitute human subjects research and require IRB review and approval or Certification of Exemption from IRB review.

IV. Authority and Responsibility of the UCLA IRB/OPRS

- A. UCLA policy requires that all research as defined in Section III(B) involving human subjects, and all other activities, which even in part involve human subjects research, regardless of sponsorship, must be reviewed and approved by the institution's IRB(s) or certified exempt from IRB review by the UCLA OPRS.
- B. Specific determinations as to the definition of "research" or "human subjects", and their implications for the jurisdiction of the UCLA IRB/OPRS under institutional policy, are determined by the UCLA IRB/OPRS.
- C. All research projects involving humans as subjects or privately identifiable human materials or data from living individuals must be reviewed and approved by the IRB(s) or certified exempt from IRB review by the UCLA OPRS prior to initiation of any research-related activities, including recruitment and screening activities. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol or the research has been certified exempt from IRB review by the UCLA OPRS.
- D. The IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects and that complies with applicable federal regulations (including 45 CFR 46, and, for FDA-regulated research, 21 CFR 50 and 56), state laws and institutional policies. Specifically:
 - 1. The IRB may disapprove, modify or approve studies based upon consideration of human subject protection aspects;
 - 2. The IRB reviews, and has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction;
 - 3. The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the investigators and auditing the conduct of the study, and observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
 - 4. The IRB may suspend or terminate approval of a study; and
 - 5. The IRB may place restrictions on a study.

V. UCLA Investigator Responsibility

- A. The Investigator is responsible for prospectively obtaining from the UCLA IRB/OPRS a determination of whether proposed research involving human subjects falls within the UCLA IRB/OPRS's jurisdiction and requires IRB review and approval or Certification of Exemption from UCLA IRB review. Please refer to [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for additional details.
- B. The Investigator is responsible for obtaining IRB review and approval or Certification of Exemption from IRB review prior to initiation of activities determined to be human subjects research. For example, the Investigator obtains IRB review and approval or Certification of Exemption from IRB review prior to engaging in interventions or interactions with human subjects in research, including recruitment, and collection of data about or samples from human subjects.
- C. The Investigator is responsible for carefully considering the likelihood that s/he will want to use clinical or routinely collected data for research purposes in the future. If it is likely, the Investigator should err on the side of inclusion and seek IRB approval prior to conducting analyses of the data for research purposes. Investigators who have the intention to use not-yet-collected clinical or routinely collected data for research purposes must seek IRB approval prior to the *collection* of the data which s/he intends to analyze.

VI. Failure to Submit a Project for IRB Review

- A. The implications of engaging in activities that qualify as human subjects research subject to IRB review or OPRS certification of exemption from IRB review without obtaining such review are significant. To do so is a violation of UCLA Policy that may result in a prohibition of publication or presentation of the research data or the use of the data to satisfy thesis or dissertation requirements.

If a UCLA Investigator begins a project for non-research purposes and later finds that the data gathered could contribute to generalizable knowledge or that he or she may wish to publish or present the results of the activities, it is important that the Investigator submit a proposal to the UCLA OPRS IRB review and approval or certification of exemption from IRB review prior to initiating analysis of the data for research purposes.

- B. Because the IRB review and certification from IRB review process is intended to prospectively ensure the protection of the rights and welfare of the human research subjects, the UCLA IRB/OPRS cannot give retroactive approval or certification of exemption for human subjects research activities, including data analysis, that were conducted prior to obtaining IRB approval or certification of exemption.
 1. If approval was not obtained prospectively, a researcher should cease study procedures, including data analysis, and contact the IRB. The researcher will be asked

- to submit an application to the IRB for review and include an explanation of why IRB approval or certification of exemption was not prospectively obtained.
2. Any human subjects research initiated or completed will be reviewed by the IRB on a case-by-case basis to determine the extent of noncompliance and whether the procedures used in the research violated any of the university's standards for the ethical conduct of research.
 3. In these cases, the IRB will decide if the investigator:
 - a. can use the data already collected;
 - b. must provide proof of informed consent, obtain permission for the use of the research data, or additional informed consent from the subjects, informing them of the deficit in the original process or providing an explanations of some other elements of the violation.
 - c. can continue the research (if not already completed); or what, if any, modifications need to be made
 - d. must destroy all data collected to date.
 4. The IRB chair will formally notify the investigator indicating the reasons for the IRB's decision, what actions the IRB is requiring, and an opportunity to respond to the Board. A copy of the notification will also be sent to the faculty advisor if the researcher is a student or to the Chair of the department if the researcher is a faculty member, the Dean of the School, and the Institutional Official.
- C. The UCLA IRB/OPRS may not approve or certify exempt applications where the Investigator has attempted to knowingly circumvent IRB/OPRS policies and procedures regarding human subjects research by collecting human subjects data without approval and then applying to use the collected data as previously existing data. It is therefore in the Investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.
- D. The UCLA IRB/OPRS is required to report all "serious or continuing noncompliance" with the federal regulations for human subjects research to the Institutional Official, OHRP, and any applicable funding agencies.
- E. The FDA may reject data that was collected without IRB approval if it is submitted in support of a marketing application.

Regulations:

45 CFR 46
21 CFR 50 and 56

References:

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) January 26, 1999 Memorandum, "Engagement of Institutions in Research".

<http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

FDA, *IRB Information Sheets: Use of Investigational Products When Subjects Enter a Second Institution*, September 1998. <http://www.fda.gov/oc/ohrt/irbs/investigational.html>

OHRP Guidance on Reporting Incidents to OHRP, May 27, 2005.

http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html