

Policy Number: 3

Title: Human Subjects Research Determinations

Date of Last Revision: July 5, 2007

I. Introduction

The UCLA OPRS/IRB has the sole authority to determine whether an activity conducted by UCLA faculty, staff, or students (or conducted on UCLA students) meets the regulatory definition of “human subjects research” and therefore requires IRB review and approval or certification of exemption from IRB review. UCLA faculty, staff, and students who intend to conduct activities that might represent “human subjects research” do not have the authority to make an independent determination that UCLA IRB review and approval or certification of exemption is not required.

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 regulation.
- E. **Coded Information:** For the purposes of this policy, identifying information 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, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- F. **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.
- G. **Exempt Human Subjects Research:** Research that involves humans and meets the conditions outlined under [*OPRS/IRB Policy 5: Certification of Exemption from IRB Review*](#).

III. Activities That Constitute “Research” As Defined By DHHS Regulations

- A. Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.
 - 1. Examples of systematic investigations include, but are not limited to: observational studies; interviews; surveys; test development; or program evaluation.

2. Examples of activities that would not normally be considered systematic investigations include, but are not limited to: (a) training activities (e.g., individuals being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques) provided that the activities are not designed to develop or contribute to generalizable knowledge; and (b) classroom exercises involving living individuals or private identifiable data about living individuals where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods and the activity is not designed to develop or contribute to generalizable knowledge.

B. Activities are not research if they are not designed to contribute to generalizable knowledge.

Examples of activities that are typically not generalizable include:

1. Biographies and service or course evaluations, unless they can be generalized to other individuals;
2. Services, courses, or concepts where it is not the intention to share them beyond the UCLA community;
3. Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices; and
4. Quality Assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share them beyond the UCLA community.

C. Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable and therefore meet the regulatory definition of research. Such thesis or dissertation projects require IRB review and approval when the research being conducted involves human subjects.

D. Oral history activities *in general* which are solely designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge are not considered research. Please refer to UCLA Human Research News, “Oral History and Human Subjects Research” (December 10, 2003)¹ for additional guidance regarding how to evaluate whether oral history activities meet the regulatory definition of “research.”

IV. **Research That Involves “Human Subjects” As Defined By DHHS Regulations**

- A. Research does not involve “human subjects” if investigators are not obtaining either:
- (1) data about living individuals through intervention or interaction with those living individuals, or
 - (2) identifiable private information about living individuals.

¹ http://www.oprs.ucla.edu/human/news/item?item_id=127350

- B. Data and private information may include specimens (see [*OPRS/IRB Policy 39: Research Involving Use of Human Specimens, and Specimen Banking*](#)).

V. Activities That Constitute “Clinical Investigations” As Defined By FDA Regulations

- A. Any use of a drug (whether approved or unapproved by the FDA) other than the use of a marketed drug in the course of medical practice is a clinical investigation (21 CFR 312.2).
- B. Any use of a medical device (whether approved or unapproved by the FDA) to determine the safety or effectiveness of that device is a clinical investigation (21 CFR 812.2(a)).
- C. Any investigation whose data will be submitted to or held for inspection by the FDA is a clinical investigation.

VI. Clinical Investigations That Involve “Human Subjects” As Defined By FDA Regulations

- A. Tissue specimens used to test the safety or efficacy of a medical device are considered human subjects under FDA regulations.
- B. If an investigator collects existing data about individuals who serve as controls for individuals who receive test articles, the control individuals are human subjects under FDA regulations.

VII. Activity(ies) That Involve Deceased Persons

- A. Research that proposes the use of only cadaver specimens is not human subjects research. Such research does not require submission to the UCLA OPRS/IRB for IRB review and approval or certification of exemption from IRB review, but may be governed by other Federal, state and local laws.
- B. Effective January 1, 2003, California law requires local IRBs to review research using State of California-produced death data files containing personal identifying information (i.e., state issued death certificates and indices).
 - 1. Research involving access to state death records that contain personal identifying information requires prospective IRB review and approval and does not qualify for certification of exemption from IRB review as the records are not publicly available. The State of California requires that researchers have a “valid scientific interest” in order for the IRB to approve such a study.

- a. State of California-produced death data files which require IRB review include:
 1. All files that can be linked to other death files using the certificate number (e.g., Death Address Files, Multiple Cause of Death Files); and
 2. All files that are provided with personal identifiers (e.g., Death Statistical Master Files, Merged Death Files, Fetal Death Statistical Master Files).
 - b. Access to State of California-produced death data files which include personal identifying information may require IRB review by both the UCLA IRB and the State of California Committee for the Protection of Human Subjects (CPHS).
2. Research involving access to death data files which are produced outside the State of California *may* not require submission to the UCLA OPRS/IRB for IRB review and approval or certification of exemption from IRB review. Investigators are responsible for identifying applicable State and Federal laws governing access to the death data files, to determine whether the applicable laws require IRB review and approval. Investigators should identify the applicable law(s) to the UCLA OPRS/IRB at the time of submission.
 3. Research involving access to State of California-produced death data files which do not contain personal identifying information does not require submission to the UCLA OPRS/IRB for IRB review and approval or certification of exemption from IRB review.
 - a. State of California-produced death data files which do not contain personal identifying information are:
 1. Death Public Use Files,
 2. Death Statistical Master Files provided without personal identifiers,
 3. Merged Death Files provided without personal identifiers, and
 4. Fetal Death Statistical Master Files provided without personal identifiers.

VIII. Investigator Responsibilities

- A. Investigators do not have the authority to make an independent determination that UCLA IRB review and approval or certification of exemption is not required.
- B. Investigators who intend to conduct activities that might represent “human subjects research” must submit a description of the proposed activities to the UCLA OPRS/IRB for a determination of whether UCLA IRB review and approval or certification of exemption is required prior to the UCLA investigator’s involvement in the proposed activities.

1. In order for the OPRS/IRB to make a determination, the description of the proposed activities should include information such as, but not limited to, the following: the purpose of the activity, methods and procedures that will be involved and how individuals (or their specimens or data) will be involved.
- C. Non-UCLA researchers **who propose to recruit UCLA students as subjects** must contact the UCLA OPRS/IRB for a determination of whether proposed research falls within the UCLA OPRS/IRB's jurisdiction and requires UCLA IRB review and approval or Certification of Exemption from UCLA IRB review. Please refer to [OPRS/IRB Policy 2: Activities Subject to UCLA OPRS/IRB Jurisdiction](#) for additional details.
- D. Investigators are responsible for replying to all UCLA OPRS/IRB requests for additional information and/or clarification necessary to make a determination as to whether proposed activities represent "human subjects research" and require prospective IRB review and approval or certification of exemption.
- E. Investigators are responsible for maintaining a copy of the UCLA OPRS/IRB's written determination whether activities do or do not constitute human subjects research.
- F. Investigators must submit to the UCLA OPRS/IRB all changes to the proposed activities, in order to obtain the UCLA OPRS/IRB's updated written determination whether the revised activities do or do not constitute human subjects research.
- G. Investigators who conduct activities which are determined to not constitute human subjects research are responsible for complying with all applicable institutional policies and procedures.

IX. UCLA OPRS/IRB Responsibilities

- A. The UCLA OPRS/IRB has sole authority to determine whether an activity represents "human subjects research."
- B. Determinations are made by an IRB Administrator, Assistant Director or the UCLA OPRS Director, in consultation with the IRB Chair or his/her designee as necessary, and will be provided to the investigator in writing.
- C. The UCLA OPRS/IRB will make a determination whether an activity is "human subjects research" by considering whether the activity either: (1) is "research" that involves "human subjects" as defined by DHHS regulations, or (2) is a "clinical investigation" as defined by FDA regulations.
- D. The UCLA OPRS/IRB may request additional information and/or clarification in order to make the determination whether activities constitute "human subjects research" and require prospective IRB review and approval or certification of exemption from IRB review.

- E. The UCLA OPRS/IRB will review all changes to the proposed activities, and provide an updated written determination whether the revised activities do or do not constitute human subjects research.

Regulations:

45 CFR 46.102

21 CFR 50.3

21 CFR 56.102 and 56.103

California Health and Safety Code Section 102231

References:

OHRP Human Subject Regulations Decision Charts, September 24, 2004

(<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>)

OHRP Guidance on Research Involving Coded Private Information or Biological Specimens,

August 10, 2004. (<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>)

State of California Center for Health Statistics Office of Health Information and Research Death Files Information page. (<http://www.dhs.ca.gov/chs/OHIR/products/deathfiles.htm>)

State of California Health and Human Services Agency, Committee for Protection of Human Subjects, Instructions for Researchers, August 2006.

(<http://www.oshpd.state.ca.us/CPHS/Instructions/InstructionsforResearchers.pdf>)

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>)

Attached:

OPRS-1 UCLA Assurance Policies

(<http://oprs.ucla.edu/human/documents/pdf/UCLA-Assurance-Policies.pdf>)

OPRS-5 UCLA OPRS Human Research News, "Oral History and Human Subjects Research," December 10, 2003.

(http://oprs.ucla.edu/human/news/item?item_id=127350)