



## Guidance: Determining Which Activities Require UCLA OHRPP/IRB Review (last updated September 25, 2020)

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## Overview

This guidance document assists UCLA investigators with determining which activities require UCLA OHRPP/IRB review. Examples of activities that may or may not require IRB review are included in this guidance. All activities that constitute “human research” that are performed by UCLA employees and students must be reviewed and approved by the UCLA IRB or be certified exempt from IRB review prior to initiation (see [UCLA Policy 991](#) for details).

**IMPORTANT NOTE:** This includes preparatory to research activities that involve interventions or interactions with living individuals, e.g., advertising, recruitment, and/or screening of potential subjects for research, and/or accessing or obtaining identifiable, private information from or about living individuals for the purpose of conducting research, e.g., review of medical records.

## Human Research Definitions

Investigators should review the following definitions to determine whether an activity is human research. They may also contact a member of the OHRPP staff for assistance with this determination. **Human Research** is any **research** or **clinical investigation** that involves **human subjects** as defined below.

### RESEARCH:

DHHS regulations define **research** as a **systematic investigation**, including research development, testing and evaluation, designed to **develop or contribute to generalizable knowledge** ([45 CFR 46.102\(d\)](#)).

### Systematic Investigation:

- A **systematic investigation** is an activity that involves a prospective plan that incorporates data collection (quantitative or qualitative) and data analysis to answer a question.
- 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.
- Examples of activities that typically **are** systematic investigations:
  - interviews and focus groups
  - surveys and questionnaires
  - analysis of data and specimens
  - observational studies

- epidemiological studies
- cognitive and perceptual experiments
- medical chart reviews
- Examples of activities that typically **are not** systematic investigations:
  - Training activities provided the activities are not designed to develop or contribute to generalizable knowledge.
  - Classroom activities 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.

### **Generalizable Knowledge:**

- Activities designed (with intent) to **develop or contribute to generalizable knowledge** are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publication or presentation).

**IMPORTANT NOTE:** The *intent* to develop or contribute to generalizable knowledge makes an activity research. Results do not have to be published or presented to qualify the activity as research.

- Examples of activities that typically **are not** designed to develop or contribute to generalizable knowledge:
  - Biographies
  - Oral histories that are designed solely to create a record of specific historical events
  - Service or course evaluations, unless they can be generalized to other individuals
  - Services, courses, or concepts where it is not the intention to share the results beyond the UCLA community
  - Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
  - Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the UCLA community

**FDA regulations** define a **clinical investigation** as any experiment that involves a **test article** and one or more human subjects, and that either subject to the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Act, or need not subject to the requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by the FDA as part of an application for a research or marketing permit ([21 CFR 50.3\(c\)](#), [21 CFR 56.103\(c\)](#), [21 CFR 312.3\(b\)](#), and [21 CFR 812.3\(h\)](#)).

- A **test article** is 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.
- Examples of activities that are **clinical investigations**:
  - Clinical trials that involve investigational drugs or devices
  - Research testing the safety and effectiveness of a device
  - Medical outcome studies comparing approved drugs or devices

## HUMAN SUBJECT:

**DHHS Regulations** define a **human subject** 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** ([45 CFR 46.102\(f\)](#)).

- **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.
- **Interaction** includes communication or interpersonal contact between investigator and subject.
- **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., 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.

**FDA Regulations** define a **human subject** as an individual who becomes a participant in research, either as a recipient of the test article or as a control ([21 CFR 50.3\(g\)](#), [21 CFR 56.103\(e\)](#), [21 CFR 312.3\(b\)](#), and [21 CFR 812.3\(p\)](#)).

- A subject may be either a healthy individual or a patient.
- Clinical investigations that use human specimens (e.g., *in vitro* diagnostic devices, assays or culture media) involve "human subjects".

**California Law** requires that an IRB confirm the existence of a valid scientific interest before **California-produced death data files containing personal identifying information** (i.e., state issued death certificates and indices held by the State Registrar, local registrars, and county recorders) may be released to researchers.

## Examples of Activities that May or May Not Require UCLA IRB Review

ACTIVITY	DESCRIPTION	IRB REVIEW
Case Report Studies	<b>Retrospective</b> review of a patient's medical record with intent to document a specific situation or the experience of an individual without intent to form a research hypothesis, draw conclusions or generalize findings. The data will be de-identified.	<b>NO if 1-3</b> <i>Greater than 3 records requires IRB approval</i>
	<b>Prospective:</b> A single subject study with clear intent, before recruiting or interacting with the participant, to use <i>data that would not ordinarily be collected in the course of treatment</i> . The intent is to report and publish the case study.	<b>YES</b>
Classroom Assignments / Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge.	<b>NO</b> <i>Instructors have an obligation to</i>

ACTIVITY	DESCRIPTION	IRB REVIEW
		<i>protect students and others</i>
<b>Clinical Investigations</b>	Experiments using a test article on one or more human subjects that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated include foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.	<b>YES</b>
<b>“Compassionate” or Treatment Use of an Investigational Drug or Device; Expanded Access Programs</b>	A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: <ol style="list-style-type: none"> <li>1. The patient has a condition that is life-threatening or a serious disease,</li> <li>2. No comparative or satisfactory alternative treatment is available,</li> <li>3. A controlled, clinical trial of drug/device is ongoing,</li> <li>4. Sponsor is pursuing marketing approval.</li> </ol>	<b>YES</b>
<b>Emergency Use of an Investigational Drug or Device</b>	A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: <ol style="list-style-type: none"> <li>1. The test article is used one time per institution to treat a single patient,</li> <li>2. The patient has a condition that is life-threatening or severely debilitating,</li> <li>3. No standard treatment is available,</li> <li>4. There is not sufficient time to obtain IRB review and approval,</li> <li>5. The emergency use is reported to the IRB within five working days; when possible, the treating physician should consult with the IRB prior to use.</li> </ol>	<b>IRB NOTIFICATION REQUIRED WITHIN 5 DAYS OF USE</b>  <i>See <a href="#">Emergency Use of Test Article</a> for more information.</i>
	Sponsor or manufacturer of the drug/device requires IRB approval to release it in an emergency use situation.	<b>YES</b>
<b>Ethnographic Research</b>	The Investigator or his/her staff will participate, overtly or covertly, in people’s daily lives for an extended period of time. They will watch what happens, listen to what is said, ask questions and collect data to create a broader understanding of a particular environment, ethnic group, gender, etc.	<b>YES</b>
<b>Evidence Based Practice (EBP) Projects</b>	EBP translates existing generalizable knowledge to implement local practice changes and/or answer a local practice question. EBP activities may include implementing practice changes on a pilot unit, evaluating process & outcomes.	<b>NO</b>  <i>Exercise of professional ethics is expected</i>  <i>Other approvals – e.g. Nursing Practice Research</i>

ACTIVITY	DESCRIPTION	IRB REVIEW
		<i>Council - may be required</i>
<b>Innovative or Novel Procedures, Treatment, or Instructional Methods</b>	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants in order to compare to standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus to develop or contribute to generalizable knowledge.	<b>YES</b>
	The use of innovative interventions that are designed solely to enhance the well being of an individual patient and have a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the particular individual.	<b>NO</b>
<b>Internet Research</b>	Online websites are set up for the purposes of collecting data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.	<b>YES</b>
<b>Journalism</b>	Activities focused on the collection, verification, reporting, and analysis of information or facts on current events, trends, newsworthy issues or stories about people or events.  There is no intent to test a hypothesis.	<b>NO</b> <i>Exercise of professional ethics is expected</i>
<b>Limited Data Set (LDS) Research</b>	LDS research does not require IRB review nor a HIPAA waiver of authorization. However, an LDS is still considered Protected Health Information (PHI), because it may contain identifiable information.  To obtain an LDS, HIPAA regulations require the researcher enter into a Data Use Agreement (DUA) with the covered entity providing the data. The DUA promises specified safeguards for the data. <a href="#">DUAs</a> are maintained by the UCLA Office of Compliance, and UCLA OHRPP is not authorized to sign DUAs.	<b>NO</b> <i>All questions regarding HIPAA in relation to LDS research should be directed to the <a href="#">UCLA Office of Compliance</a>.</i>
<b>Oral Histories</b>	Interviews that collect, preserve and interpret the voices and memories of people, communities, and participants in past events as a method of historical documentation.  The intent is to document a particular past or unique event in history.	<b>NO</b> <i>Exercise of professional ethics is expected</i>
<b>Pilot Studies</b>	Pilot studies that meet the definition of human research, regardless of the number of subjects enrolled or the duration of the studies.	<b>YES</b>
<b>Quality Assurance (QA) and Quality Improvement (QI) Activities</b>	<b>Clinical QI/QA:</b> Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs or business practices in the local setting. Intent is limited to improving care, operations, etc.	<b>No</b>
	<b>Non-clinical QI/QA:</b> Data collected with the limited intent of evaluating and improving existing services and programs or for	<b>No</b>

ACTIVITY	DESCRIPTION	IRB REVIEW
	<p>developing new services or programs. Examples include teaching evaluations or customer service surveys. Intent is limited to evaluating services or programs.</p>	
	<p>When proposed QI/QA activities may have a research intent, (1) review the references below and (2) contact the <a href="#">SGIRB Administrator</a> or <a href="#">NGIRB Administrator</a> for assistance: References:  <ul style="list-style-type: none"> <li>• <a href="#">Quality Improvement or Research Worksheet</a></li> <li>• <a href="#">“Quality Improvement or Research? Implications of OHRP’s Response to the Keystone: ICU Project.”</a> (Rachel Nosowsky, American Health Lawyers Association)</li> <li>• <a href="#">UCLA OHRPP Flowchart to Determine if UCLA IRB Approval Required For Quality Improvement (QI) Projects</a></li> </ul> </p>	<p style="text-align: center;"><b>Maybe</b></p> <p style="text-align: center;"><i>See flowchart and worksheet referenced at left for additional direction</i></p> <p style="text-align: center;"><i>Contact <a href="#">UCLA OHRPP staff</a> for guidance</i></p>
<p><b>Repositories and Registries (e.g., data, specimens)</b></p>	<p>A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple investigators or multiple research projects.</p>	<p><b>YES</b></p>
	<p>Storage of human tissue, blood, genetic material or data that has been de-identified by UCLA personnel at the time of collection. See <a href="#">Collection, Use, Sharing and Secondary Analyses of Human Specimens and/or Data for Research Purposes</a>.</p>	<p style="text-align: center;"><b>YES</b></p> <p style="text-align: center;"><i>some activities may not require IRB review</i></p>
<p><b>Standard Diagnostic or Therapeutic Procedures</b></p>	<p>The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.</p>	<p><b>YES</b></p>
	<p>Alteration in patient care or assignment for research purposes.</p>	<p><b>YES</b></p>
	<p>A diagnostic procedure added to a standard treatment for the purpose of research.</p>	<p><b>YES</b></p>
	<p>An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a patient but not for the purposes of research.</p>	<p><b>NO</b></p>
<p><b>Student Conducted Research</b></p>	<p>Thesis or dissertation projects conducted to meet the requirements of a graduate degree. See <a href="#">Research Conducted by UCLA Students</a>.</p>	<p><b>YES</b></p>
<p><b>UCLA serving as the Coordinating Center for a Multi-center Research Project</b></p>	<p>UCLA <i>is not</i> an enrolling site and the UCLA PI has agreed to serve as the coordinating center for a multi-center trial, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.</p>	<p><b>YES</b></p>
	<p>UCLA <i>is</i> an enrolling site and the UCLA PI has agreed to serve as the coordinating center for the multi-center trial, which may include activities such as data collection, data analysis, reporting of adverse events to regulatory authorities, and/or oversight of the research at participating sites.</p>	<p><b>YES</b></p>

## Regulations and References

### DHHS:

- [45 CFR 46.102](#)

### FDA:

- [21 CFR 50.3](#)
- [21 CFR 56.102 and 56.103](#)
- [21 CFR 312.3\(b\)](#)
- [21 CFR 812.3\(h\)](#)

### CA Statute:

- [California Health and Safety Code 102231](#)

### References:

- [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#)
- [OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](#)
- [OHRP Human Subject Regulations Decision Charts](#)
- [UCLA Policy 991: Protection of Human Subjects in Research](#)

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### Change history:

6/9/2016: Added guidance re: Evidence Based Practice; corrected guidance re: California law re: death data files; updated links.

5/21/2020: Added guidance re: Limited Data Set; updated links.

9/25/2020: Updated the links in the Quality Assurance (QA) and Quality Improvement (QI) Activities References section.