Getting Started with an IRB Application
A Guide for Investigators and Research Staff

Below is a list of suggestions on how to get started, resources needed, and an overview of the submission process.

Overview
The UCLA Institutional Review Boards (IRBs) are the committees designated by UCLA to review the conduct of research involving human subjects that is conducted by UCLA faculty and staff (conducting studies involving human subjects within the course and scope of their duties) as well as UCLA students (conducting studies involving human subjects within the course of their studies).

Non-UCLA investigators wishing to access any UCLA facilities, patients, or personnel (faculty, staff or students) for human subjects research to submit an Application for Administrative Review to the UCLA OHRPP for confirmation that the research does not require UCLA IRB review or Certification of Exemption from UCLA IRB review.

The UCLA Office for the Human Research Protection Program (OHRPP) is the office that supports the 5 UCLA IRBs. Each of the five IRBs specialize in certain types of research. See the description of their specialties.

The OHRPP staff serve as liaisons between the IRBs and researchers, and are a resource to support researchers in their applications to and communications with the IRBs. Please contact us with any questions! You may reach us at:
GCIRB@research.ucla.edu (non-medical research)
MIRB@research.ucla.edu (medical research)

Contact information for individuals is located in the OHRPP Staff Directory.

Determine if UCLA IRB Review is Required
First, determine if the activities meet the federal definition of "research" involving "human subjects". Any research that involves either the participation of human subjects or the use of human biological specimens, medical charts, or databases with identifying information about humans is considered to be human subject research and requires review.
These guidance documents will help you to determine whether your activity meets the definition of research involving human subjects:

- Determining Which Activities Require UCLA OHRPP/IRB Review and
- Determining When Collection or Use of Data and Specimens for Research Requires IRB Review
- Research Conducted by UCLA Students

**IMPORTANT NOTE:** IRB review and approval or certification of exemption must be obtained prior to any contact with human subjects or any use of their specimens, records, or data.

**Complete Training Courses**

Once you have determined that the activities are research involving human subjects, complete the training courses:

**Human Subjects Ethics and Regulations:**

- All key research personnel who will work with human subjects must complete the Collaborative Institutional Training Initiative (CITI) Online Human Subjects Protection Training before submission to the IRB. See a definition of Key Personnel.

**Submit to the IRB:**

- For current information on our IRB application system, please see Electronic Submission Systems.

**Assess Risk & Determine Level of Review**

The risk level and types of research procedures will determine which level of review is required. To determine the risk level of your research, see "Conducting Risk-Benefit Assessments".

Exempt Certification:

- Technically exempt from the need for IRB review, but requires submission of an application, and OHRPP confirmation of the certification of exempt status.
- OHRPP Guidance on Certification of Exemption from IRB review including details of Exemption categories

IRB Review - See Level of IRB Review - Expedited Review and Full Committee Review

- Expedited
  - No more than minimal risk: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
  - Reviewed by a representative or subcommittee of the IRBs.
  - List of the Expedited Review categories.
  - EXAMPLES: Standard quality of life survey, in-person interview about non-sensitive topics.
• **Full Committee:**
  - More than minimal risks to subjects
  - Reviewed by one of five convened IRBs.
  - EXAMPLES: Randomized double blind clinical trial of investigational drug to treat terminal disease; behavioral intervention to reduce drug use; one-on-one interviews with a vulnerable population about sensitive topic where privacy and confidentiality cannot be guaranteed.

**IMPORTANT NOTE:** This determination will help you allow for sufficient time for review of your protocol.

**Allow Sufficient Time**
The length of time for review and approval depends on the type of human research, the level of risk, and the complexity of ethical or technical questions that arise during review.

**Full committee review:**
- Allow 6-8 weeks for Full Committee approvals of initial submissions and modifications.
- Allow 4 weeks for Full Committee approval of continuing review submissions.
- Each of the 5 IRBs meet twice monthly: [IRB meeting dates and application deadlines](#).

**Expedited and Exempt review:**
- Allow 2-3 weeks for Expedited approvals.
- Allow 1 week for Exempt certifications.
- Allow 1 week for renewals and modifications to expedited and exempt studies.
- Exempt and expedited applications are reviewed in the order received and do not have application deadlines.

Allow extra time during holiday and vacation periods.

**Apply for IRB Review**
All levels of review use the same webIRB application; the application is designed to branch in response to the information provided about the study procedures.

Develop or collect the following **Materials Required for IRB Review** before completing the IRB application:
- Funding application (if funded)
- Recruitment and screening materials (flyers, letters) (See [Guidance and Procedure: Recruitment and Screening Methods and Materials](#))
- Consent and assent forms (See [Consent, Assent, and Screening Templates](#))
- Study measures
- If applicable: Investigational Drug/Device Brochures, Package Inserts, Sponsor’s protocol
Understand the IRB Review Process

Pre-Review:
- OHRPP staff perform an administrative pre-review of submissions to ensure that the information and materials required for the Board to complete their review are included.
- OHRPP staff may send requests to obtain the necessary information. (EXAMPLES: Consent forms are missing, a recruitment process is not described)

IMPORTANT NOTE: Administrative pre-review does not include scientific or scholarly review

Review:
- IRB members review all information and materials provided in the IRB application. *Investigators are not routinely invited to attend IRB meetings for the review process.*

Post Review:
- During the IRB review, you will likely be asked to discuss different aspects of your research, or add information to your application.
- OHRPP staff will communicate the IRB’s decisions and requests to researchers.
- Researchers need to provide the requested information and materials and complete the requested revisions in order to complete the IRB review process.

See detailed explanation of the process of Communication of IRB Actions

Understand Your Responsibilities

- Obtain prospective IRB approval for modifications to previously approved research.
- Obtain IRB continuing review annually, if applicable, or complete annual PI assurance.
- Submit post-approval reports of events that are unanticipated problems that may adversely affect the safety of participants or the conduct of the research, and any information relevant to the conduct of the approved research.
- Submit closure report when research is complete.

Ask Questions

Please ask questions at any stage of the process. The OHRPP is available and can help facilitate the review. You may reach us at:
GCIRB@research.ucla.edu (non-medical research)
MIRB@research.ucla.edu (medical research)

Each of the five IRBs specialize in certain types of research. See the description of their specialties.

Staff who support each IRB can be identified in the OHRPP Staff Directory.