

Guidance and Procedure Number: 64
Title: HRPP Education and Training
Date of Last Revision: April 7, 2009

I. Introduction

UCLA requires a basic level of training for all individuals who are involved in the performance or oversight of human subject research. The type and amount of training is dependent on the individual's role. A variety of resources are available for supplemental as well as additional basic training. The primary training groups include:

- Investigators and Research Staff
- IRB Members
- HRPP Staff
- University Officials & Staff

II. Core Education & Training

A. Investigators and Research Staff

Human Subjects Protections: All members of the research team who will have contact with subjects and/or identifiable research data (including coded data) must complete training through the CITI Collaborative Institutional Training Initiative [Collaborative Institutional Training Initiative](#) (CITI) prior to approval of their research. The certification requirement is applied regardless of funding source. The requirement also applies to protocols that are certified exempt from UCLA IRB review. Faculty Sponsors, because they are considered the responsible parties for the legal and ethical performance of student projects, must also complete CITI certification.

The CITI course is designed to help investigators identify those research activities which involve human subjects and to understand how to protect the rights and welfare of all human subjects involved in research.

Upon registering with CITI, UCLA users will be asked to identify their Learner Group. The Learner Group designation determines the courses they are required to complete. Investigators and research staff may choose to complete one of the following three learner groups:

- Biomedical Research
- Social& Behavioral Research
- Data or Specimens Only Research

Researchers will be required to take CITI refresher training every three years.

HIPAA: Completion of the online HIPAA Clinical Research Training Course is required for all investigators and research staff who will have access to protected health information in UCLA medical records: [UCLA Online HIPAA](#)

Human Research News: Investigators are encouraged to subscribe to the *Human Research News* e-mail listserv so that they receive updates on issues regarding the conduct of human subject research: [Subscribe to Human Research News](#)

Campus Consults: The UCLA HRPP Office offers [consulting services](#) to investigators and research staff preparing IRB submissions or responses.

B. IRB Members

Orientation Session: All new IRB members participate in a 1-2 hour orientation session with the Assistant Director and Committee Administrator, which includes an overview of the IRB process, *The Belmont Report*, federal regulations 45 CFR 46 and 21 CFR 50 and 56 (for MIRB members only) and other applicable federal and state regulations. All members are given a copy of the *Institutional Review Board Member Handbook* by Robert J. Amdur, M.D. and an orientation packet with links to web references and UCLA specific information.

CITI Training: IRB Members must complete a specific set of CITI courses specifically designed for IRB members. Recertification is required every three years.

Ongoing Education:

- Members are provided with the journal *IRB: Ethics and Human Research*.
- Articles from scientific literature and appropriate educational materials are periodically included in the IRB meeting packet
- Regular monthly training sessions for both members and staff are presented on current issues as well as topics covered in the *Institutional Review Board Member Handbook*. Additionally, upon request or on an as needed basis, information on selected topics is presented to the Board by HRPP Staff.
- Each year a number of IRB Chairs and members are invited to attend national conferences on the protection of human research subjects.
- Members receive the [Human Research News](#). News items may appear on the IRB agendas for further discussion.

C. HRPP Staff

Orientation: In addition to the training provided to IRB members, all staff are trained on a day to day operations of the program. Staff are also given a copy of the *Institutional Review Board Member Handbook* by Robert J. Amdur, M.D as well as an orientation packet with links to web references and UCLA specific information. HRPP "All Staff" training meetings are conducted monthly and the Medical IRBs and General Campus IRBs hold separate monthly training meetings as well. Administrator group training meetings are on-going and address relevant issues.

CITI and HIPAA Training: During the orientation period, all HRPP Staff must complete the CITI and HIPAA Training modules: [CITI Collaborative Institutional Training Initiative](#) and [UCLA Online HIPAA](#).

Council for Certification of IRB Professionals:

OPRS HRPP staff who meet the eligibility requirements for the CIP examination for IRB Professionals must take, pass and be certified by the Council for Certification of IRB Professionals: [CIP Certification](#)

Ongoing Education:

- On the job training is conducted through discussions of regulatory and ethical issues that arise during the processing of research proposals. Additionally, staff members are regularly provided with detailed oral and written feedback regarding their application of federal and state regulations and university policy to their work, quality of documentation, and the clarity of the information that they provide to investigators.
- Participation in the following activities is expected of all HRPP staff members:
 - Monthly HRPP “All Staff” training meetings
 - Separate monthly Medical and General Campus HRPP staff training meetings
 - On-going and specific administrator training meetings
 - Attendance at all-staff meetings and meetings for their specific work group is required
- Staff are encouraged to read the [IRB Discussion Forum](#), which promotes the discussion of ethical, regulatory and policy concerns with human subjects research
- Staff members are required to sign up for the *Human Research News* e-mail listserv.

Additional Training and Education:

- OPRS HRPP Staff have an opportunity to participate in a wide variety of developmental programs to build job skills and to foster career development. Classes and workshops, career programs, management development, and training certificate programs are available to all qualified staff. Examples of available programs are:
 - [Training Classes & Workshops](#)
 - [Training Certificate Programs](#)
 - [Career Development Programs](#)
 - [Management Development Programs](#)

D. University Officials and Staff

Education and Training:

- University Officials and staff have access to the [OPRS website](#), which includes: Federal regulations and state law; Contact information; What's New; Information for Researchers, e.g., calendar of IRB meetings, application forms, guidance, procedures and policies; Other resources; Information for research participants; and, UCLA's federalwide assurance.

- University Officials and Staff may participate in and attend training and educational sessions offered to faculty researchers, staff and students as well IRB members and HRPP Staff.
- University Officials and Staff who are a part of the HRPP are required to take the CITI course for Institutional Officials and Staff

III. Additional Education and Training Resources

A. Lectures and Workshops

- HRPP Staff conduct in-person educational sessions for small groups, including undergraduate honors or research methods classes, graduate classes, faculty development sessions, and fellowship seminars. Sessions may include an overview of the history of human subjects research and a discussion of the ethical principles underlying the conduct of human subjects research. Information regarding the federal regulations governing the conduct of human subjects research is provided along with guidance on submitting applications to the OPRS. Sessions may also be arranged regarding topics of relevance to the particular audience via an [online request form](#).
- UCLA offers training and educational opportunities for clinical research professionals through Campus Human Resources. Workshops available for staff and faculty involved in conducting clinical research include: Subject Advocacy and the Informed Consent Process, IRB Submission Workshop and Data Safety Monitoring in Clinical Research.

B. National Conferences and Workshops

- [Public Responsibility in Medicine and Research \(PRIM&R\) Conferences](#)
- [Office for Human Research Protections \(OHRP\) Workshops](#)
- [Association for the Accreditation of Human Research Protection Programs Conferences](#)

C. IRB Guidance and Forms

- Educational topics are available on the OPRS website along with guidance, resource documents, application forms and links to agencies.
 - *IRB Guidance:* Human research policies, guidance and procedures applied by the UCLA Institutional Review Board (IRB) members and staff. <http://www.oprs.ucla.edu/human/policies-guidance>
 - *IRB Forms and Guidance:* <http://www.oprs.ucla.edu/human/forms/>
- Updates and additions to the HRPP Education Program as well as a schedule of presentations are accessible by subscription to the [Human Research News mailing listserve](#):

D. CITI Training

CITI Training offers training modules on a variety of topics in addition to the required training for investigators and research staff, IRB members, HRPP Staff and Institutional Officials and staff. [CITI Collaborative Institutional Training Initiative](#)

E. Quality Improvement Program (QIP)

Investigators and research staff who participate in a [QIP protocol review](#) receive specific feedback and education on any regulatory issues identified during the review.

F. References and Online Resources

[Office of Human Research Protections](#) (OHRP)

- [The Belmont Report](#)
- [Title 45 CFR 46: Protection of Human Subjects](#)
- [Policy guidance and documents](#)
- [Inclusion of Children Policy Implementation Page](#)
- [Privacy Protection using Certificates of Confidentiality](#)
- [OHRP Frequently Asked Questions](#)

[Food and Drug Administration](#) (FDA)

- [21 CFR Part 50](#) - Protection of Human Subjects
- [21 CFR Part 56](#) - Institutional Review Boards
- [21 CFR Part 312](#) - Investigational New Drug Applications (INDs)
- [21 CFR Part 812](#) - Investigational Device Exemptions (IDEs)
- [Information Sheet Guidances](#) for IRBs, Investigators and Sponsors
- [FDA Frequently Asked Questions](#)

[California Law \(Statutes\)](#)

[California Protection of Human Subjects in Medical Experimentation Act](#)

[NIH and Clinical Research](#)

• On line glossaries:

- [Medline Plus Medical Dictionary:](#)
- [MediLexicon](#)
- [Social Psychology Glossary:](#)
- **Reference Library:** The OPRS HRPP maintains a list of reference books that are available upon request. This list is kept on the computer drive that is shared by staff and is posted in the offices that are used by the Chairs for expedited reviews.