Guidance and Procedure: OHRPP Education and Training

(last updated 8/24/2011)

Overview

UCLA provides training in the critical area of the protection of human research participants through various venues and via various methods. Many training programs are provided within the University's institutes, departments and units; others are open to a wider set of people. A few of the training programs are included in the References section below. This guidance provides information about the training offered through the UCLA Office of the Human Research Protection Program (OHRPP) as well as for the IRB members and for OHRPP staff. In general, the training requirements depend on an individual's role in HRPP. The educational requirements in this document are described for the primary training groups:

- Investigators and Research Staff
- IRB Members
- OHRPP Staff

A brief discussion of how the overall training is evaluated is also included in this guidance.

Required Training for All Researchers, Research Staff, IRB Members and OHRPP Staff

Collaborative Institutional Training (CITI): CITI is a web-based training program in human subjects protection. As of January 2011, the CITI program is used by over 1500 participating institutions and facilities around the world.

All members of the research team who will have contact with participants and/or identifiable research data (including coded data) must complete the Human Subjects Protection Course offered through the Collaborative Institutional Training Initiative (CITI) prior to approval of their research. The training 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 the Human Subjects Protection Course. IRB Members and OHRPP staff must also complete this training.

The CITI course includes a section discussing the three ethical principles described in the Belmont Report: respect for persons, beneficence and justice. Beyond that, the 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 modules they are required to complete. Investigators and research staff may select one of the following seven learner groups:

- **Biomedical Researchers & Staff**: Investigators/staff submitting to the Medical IRBs
- **Social & Behavioral Researchers & Staff**: Investigators/staff submitting to the General Campus IRBs
- **Basic Scientists/Investigators** who work with coded or identifiable data and/or specimens but who do not have contact with research participants
- **General Campus IRB Committee Members**
- **Medical IRB Committee Members**
- **OHRPP Staff**: staff employed by UCLA Office of the Human Research Protection Program

CITI refresher training is required every three years. See the CITI FAQ section of the UCLA OHRPP website for answers to frequently asked questions.

HIPAA Training:

- Completion of the online UCLA HIPAA Course through CITI is required for all investigators, research staff, IRB members and OHRPP staff.

- DGSOM HIPAA Training: Unrelated to the IRB requirements, every member of the workforce at the David Geffen School of Medicine, UCLA Hospital System and the Faculty Practice Group (FPG) is also required to take the training provided at this link: Health Insurance Portability and Accountability Act (HIPAA) Privacy & Security Workforce Training.

webIRB Training Sessions and Workshops***:*** OHRPP offers training sessions on using the on-line web-based submission system (webIRB) both for new users and experienced users. Workshops are also offered assist researchers and study team with completing their webIRB application. Training in webIRB is required of IRB members and OHRPP staff.

Additional Education and Training Resources Available through OHRPP

The OHRPP provides the following optional education and training resources to the research community:

webIRB Application
The on-line web-based IRB submission and review system at UCLA is called webIRB. The webIRB application branches to items depending on the answers to key questions. Throughout the application there is help text. This text provides guidance that is both regulatory and technical. In addition, there are links to various guidelines and other sources of information about human subject protection.

The OHRPP Web Site
The website contains a considerable amount of information for the research community including but not limited to the link to the webIRB application, the consent form templates, policies and guidance, meeting calendars, important updates, checklists for members and researchers, and contact information. Information on the website is updated frequently.

OHRPP Noontime Education Series and Learn at Lunch
OHRPP offers lectures and workshops on various topics pertaining to the conduct of human subject research through the both the “Noontime Education Series” which is geared towards

general IRB topics and the "Learn at Lunch Series" which covers topics of particular interest for clinical researchers**.** Both are held once a month during lunch hours.

OHRPP Education and Training upon Request

In-person presentations and workshops on various topics related to human subjects protection are available upon request for interested faculty, research staff and students. Though training may be tailored for specific needs, some examples of general topics are listed below:

- Successfully Preparing a Full Committee Review Application
- Tips for Speeding Up Approvals of Biomedical Applications
- Tips for Speeding Up Approvals of Social Behavioral Applications
- Post Approval Event Reporting (Adverse Events, Incidents, Violations)
- Preparing Consent and Assent Forms
- Research Using Human Biological Specimens
- Research Involving Children
- Conducting Research in an International Setting
- Using Investigational Drugs and/or Devices in Research
- Good Clinical Practice (GCP) Training

Researchers can use this Human Research Training Request Form to request a specific or tailored presentation. Researchers may also click here for contact information for the Directors or Assistant Directors to discuss particular needs.

Human Research News and Human Research Alerts

UCLA researchers and IRB members 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. OHRPP staff are required to subscribe to this listserv. The *Human Research Alerts* are sent out to remind people of upcoming training opportunities or webIRB issues.

OHRPP Kinross Consults

IRB consulting services are available to UCLA investigators and research staff preparing IRB submissions (new, continuing and amendments) or preparing responses to committee correspondence. The consultants are experienced senior staff. This service is free of charge. Click on the link above for more information.

OHRPP Quality Improvement Unit (QIU) On-Site Reviews of Human Research Studies

Investigators and research staff may request an on-site review of a clinical study and receive protocol-specific feedback and education.

Additional Training for IRB Members

In addition to the training requirements and opportunities described above, IRB members also receive the following training:

- ***Orientation Session:*** All new IRB members participate in a 1-2 hour orientation session with the Assistant Director and Committee Administrator. This session includes an overview of the IRB process, the three basic ethical principles of the Belmont Report, federal regulations 45 CFR 46 for all members as well as 21 CFR 50 and 21 CFR 56 for members of the Medical IRBs, UCLA policy and guidance, and other applicable state laws and county requirements. All members are given a copy of the *Institutional Review Board Member Handbook* by Robert J. Amdur, M.D. and the OHRPP New Member and Staff Reference List with links to web references and UCLA specific information**.**

- ***Ongoing Education:*** The following are examples of ongoing education:
  - Copies of the journal *IRB: Ethics and Human Research are distributed every two months.*

- Regular monthly presentations occur for both members and staff 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 are presented.
- Articles from scientific literature and appropriate educational materials are distributed as appropriate or relevant.
- Each year a number of IRB Chairs and members are invited to attend national or regional conferences on the topic of human research participant protections.

Additional Training for OHRPP Staff

In addition to the training requirements and opportunities described above for the research community, and the training described above for the IRB members, OHRPP staff receive the following additional training:

- ***Ongoing Education:*** All OHRPP staff members are required to participate in the following activities:
  - Quarterly OHRPP all staff training meetings
  - Separate monthly Medical and General Campus OHRPP staff training meetings
  - On-going and specific administrator training meetings

- ***Workshops, Conferences and Webinars:***
  - Senior staff attend PRIM&R conferences yearly or every other year.
  - Other staff are invited to attend regional conferences when appropriate.
  - All staff are asked to attend various webinars that are offered by PRIM&R, Huron, and AAHRPP. IRB Members may also attend if interested.
  - The Director and Assistant Director attend AAHRPP conferences when possible.

- ***Council for Certification of IRB Professionals:*** OHRPP staff members at the Coordinator level and above positions who meet the eligibility requirements for the Certification of IRB Professionals (CIP) are asked to take and pass the CIP exam to be certified by the Council for Certification of IRB Professionals and to maintain this certification.

- ***Professional Development:*** OHRPP staff members have an opportunity to participate in a wide variety of developmental programs to build job skills and to foster career development through the UCLA Campus Human Resources' Training and Development Unit. Classes and workshops, career programs, management development, and training certificate programs are available to all qualified staff.

Evaluation of Educational Activities

The human subject protection training requirements and the effectiveness of the OHRPP educational activities are monitored and evaluated in various ways:

- IRB approval for new and continuing studies is contingent upon current CITI training requirements being met. This is monitored by the Protocol Review staff and the QIU staff.
- The UCLA Health System monitors the training for HIPAA privacy and security in the workplace.
- The Noontime Education Series, the Learn at Lunch Series, and the webIRB Training as well as most ad hoc presentations provide participants with a brief evaluation form to complete at the end of the session. These are analyzed and improvements are made based on comments.
- The results ***QIU on-site visits*** provide information about which areas researchers need more training in.

- The ***QIU*** evaluates post approval event reports to determine if there are trends that reflect areas of needed training.
- ***IRB Members*** are evaluated annually by the Chairs and Assistant Director. At this or any time they can identify the areas in which they need or want more training.
- ***IRB Chairs*** are evaluated annually by the OHRPP Director and IRB Administrator.
- ***IRB Members*** also provide feedback to the OHRPP staff about common areas that investigators make mistakes in so that additional training can be provided.
- ***OHRPP*** staff members are formally evaluated annually by their supervisors.
- ***The OHRPP Director*** monitors IRB review and approval times as an indicator not only of the IRB efficiency but also as a measure of how straightforward the application process is.

References and Resources

UCLA Training and Education

- Many UCLA departments and institutes offer training programs that include information about human subject protection issues. Researchers should check the bulletins and announcements from their schools and departments.
- CTSI IRB web page lists upcoming events and training.
- Ethics in Patient-Oriented Research: A ten-week course offered through the School of Medicine that provides a thorough background in the ethical issues in research with emphasis on research involving humans.
- K30 Program: Graduate Training Program in Translational and Clinical Investigation

UCLA Campus Human Resources Training and Development
UCLA offers various training and educational opportunities for clinical research professionals. Workshops available for staff and faculty involved in conducting clinical research include:

- Research Advocacy and the Informed Consent Process
- Data and Safety Monitoring in Clinical Research
- Good Clinical Practices: Source Documentation and Data Management

California Health and Safety Code

- Section 24170-24170.5 - Protection of Human Subjects in Medical Experimentation Act

DHHS Office of Human Research Protections (OHRP)

- The Belmont Report
- Title 45 CFR 46: Protection of Human Subjects
- Policy guidance and documents
- OHRP Frequently Asked Questions

Food and Drug Administration (FDA)

- 21 CFR Part 50 - Protection of Human Subjects
- 21 CFR Part 56 - Institutional Review Boards
- Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors
- FDA Frequently Asked Questions

National Conferences and Workshops

- Public Responsibility in Medicine and Research (PRIM&R) Conferences
- Association for the Accreditation of Human Research Protection Programs (AAHRPP) Conferences