

Policy Number: 62

Title: Investigator and Key Personnel Training

Date of Last Revision: July 5, 2007

I. Certification in the Protection of Human Research Subjects

The IRBs require that all members of the research team who will have contact with subjects and/or identifiable research data (including coded data) must complete UCLA's Protecting Human Research Subjects (PHRS) education course. Faculty Sponsors, because they are considered the responsible parties for the legal and ethical performance of student projects, must also complete the PHRS course.

The certification requirement is applied regardless of funding source. The requirement also applies to protocols that are certified exempt from UCLA IRB review.

The PHRS 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. The web-based training program¹ uses some materials available from NIH and some materials specifically developed for UCLA.

Training and testing may be accomplished on-line and a certificate will be printed out upon completion of the course. Certification is available for either biomedical research or social behavioral research; investigator and key personnel should complete the course most applicable to their research. In some cases, depending on the research, investigators and key personnel may need to complete both courses.

Users are only required to complete the certification process once and certificates do not expire. Completion of this course does not ensure IRB approval for any or all proposals submitted to the IRB.

A. Prerequisite Modules

All investigators and key personnel must complete the first four prerequisite modules and their associated quizzes:

1. Introduction
2. Federalwide Assurance
3. FWA Quiz
4. IRB Review

¹ <http://www.training.ucla.edu/>

5. IRB Quiz
6. Ethical Issues
7. Ethical Quiz

B. Biomedical and Social Behavioral Submodules

Once the prerequisite modules are completed, investigators and key personnel should complete either the biomedical researchers modules or the social behavioral researchers modules to complete the training and obtain the applicable certification.

Biomedical Researchers Modules:

1. Biomedical Module
2. Biomedical – Informed Consent
3. Informed Consent Quiz
4. Biomedical – Data and Safety Monitoring
5. Biomedical – Genetic Testing of Biological Samples
6. Biomedical – Case Studies

Social Behavioral Researchers Modules

1. Social – Introduction
2. Social – Level of Review
3. Social – Risks
4. Social – Informed Consent
5. Social – The Consent Process

C. Non-UCLA key research personnel

The UCLA IRBs will require assurance that non-UCLA key research personnel² will obtain UCLA PHRS certification in the following cases:

1. The non-UCLA affiliated researcher will be recruiting or consenting subjects or conducting research procedures on UCLA premises;
2. When UCLA is the coordinating center for the research, the UCLA IRBs require certification from those researchers whose institutions neither receive NIH funding nor have a certification requirement. For participating sites with certification requirements, only IRB approval from their institution is required; or
3. The qualifications described in (2) apply also for proposed research which involves collaborating institutions (coordinating center NOT identified or non-existent) who will be sharing identifiable research data or specimens (including coded data or specimens) with UCLA (and vice versa).

² Key research personnel: Any person who will recruit, screen, or consent subjects OR any person who will have contact with identifiable research data (including coded data).

II. HIPAA Certification

For research involving access to UCLA medical records, the IRBs require that all members of the research team who will access Protected Health Information complete the HIPAA Clinical Research Training Course. Training may be accomplished on-line³ and a certificate will be printed out upon completion of the course. Users are only required to complete the certification process once and certificates do not expire.

III. OPRS Website (<http://www.oprs.ucla.edu/human/>)

The OPRS website provides the UCLA research community with immediate access to a comprehensive set of policies, guidance, forms and checklists. The website also includes the *Investigator's Manual for the Protection of Human Subjects*, a reference for investigators which details the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the UCLA IRBs. Members of the research community should familiarize themselves with the contents of the OPRS website, especially those policies and sections of the manual that address their specific research activities. Since the field of human subject protection is constantly evolving, sections of the website are subject to change. OPRS maintains the website and keeps the UCLA research community apprised of important changes.

IV. UCLA Human Research News

The IRBs send mass email notifications to investigators subscribing to the UCLA Human Research Email News, to alert them of pertinent IRB issues, regulations, laws or guidelines relevant to research involving human subjects. Human Research News is also posted on the OPRS web site.⁴

V. Campus Human Resources Training and Development Courses

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.

³ <http://www.training.ucla.edu/>

⁴ To subscribe to the Human Research News e-mail list, please visit <http://lists.ucla.edu/cgi-bin/mailman/listinfo/investigators-l> and provide the needed information in the section entitled "Subscribe to Investigators-l."

VI. OPRS Presentations

- A. Upon request, OPRS 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 more specific topics of relevance to the particular audience.
- B. OPRS staff also conduct in-person education sessions to introduce key policy changes or other developments in human subject protections. Announcements regarding such developments will include information about any related training offered.

VII. OPRS Responsibilities

- A. OPRS shall maintain a functional and navigable website as the primary means of communication with the UCLA research community and as the primary source of forms and other materials needed by the research community for submissions of research for review.
 - 1. OPRS shall also disseminate information via other means, such as printed announcements, in-person presentations and e-mail lists, in order to ensure that important information is disseminated as widely as possible.
- B. OPRS shall maintain a web-based training program as the primary method of providing basic, introductory training to the UCLA research community.
 - 1. Such web-based training shall provide separate tracks that address the distinct needs of biomedical researchers and sociobehavioral researchers.
- C. OPRS shall regularly assess the training and education needs of the various audiences making up the UCLA research community. Such needs assessment shall occur by multiple methods, including but not limited to:
 - 1. Surveys, questionnaires and evaluation forms
 - 2. Meetings with groups that have sustained, frequent interaction with the IRBs and OPRS
 - 3. Periodic solicitation of feedback from IRB members and staff regarding consistent or significant problems seen in submissions for IRB review
 - 4. Informal conversations with members of the UCLA research community

- D. OPRS shall seek feedback regarding the quality of education and training from those who use OPRS materials or attend OPRS-held sessions.
- E. OPRS shall use feedback and the results of needs assessments to guide the types of training desired or needed by the UCLA research community and revision of materials.
- F. The OPRS Director and Assistant Director (Education and Policy) shall assess the quality of the OPRS training and education program on a regular basis, but no less than annually. The assessment shall ensure the following:
 - 1. Needs assessment and evaluation are being conducted according to this policy
 - 2. The program is modified in response to valid feedback obtained through needs assessment and evaluation
 - 3. Materials and information remain current and accessible. This will include evaluation of the functionality of the OPRS website to ensure that broken links are fixed in a timely fashion

References:

UCLA's Protecting Human Research Subjects (PHRS) education course:

<http://www.training.ucla.edu/ucla/>

NIH Notice OD-00-039, "Required Education In The Protection Of Human Research Participants," June 5, 2000.

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>)