

**Policy Number: 64**  
**Title: IRB Staff Training**  
**Date of Last Revision: July 5, 2007**

**I. IRB Staff Qualifications**

- A. Selection: Qualified applicants are interviewed by UCLA OPRS management, including assessment of oral and written skills.
- B. Requirements: Education and skill requirements are outlined in the job descriptions for the respective positions.

**II. Training of New IRB Staff**

- A. New staff members are given an orientation binder that includes the following documents and educational materials:
  - 1. The Belmont Report
  - 2. Declaration of Helsinki
  - 3. Code of Federal Regulations
  - 4. 21 CFR 50 [M-IRB staff only]
  - 5. 21 CFR 56 [M-IRB staff only]
  - 6. 45 CFR 46
  - 7. "FDA Information Sheets" [M-IRB staff only]
  - 8. UCLA Federalwide Assurance
  - 9. UCLA's Investigator's Manual for the Protection of Human Subjects
  - 10. UCLA's IRB Standard Operating Procedures
  - 11. Vice Chancellor Roberto D. Peccei's November 2004 institutional message
  - 12. UCLA Human Research Policy Board Policy Statements
  - 13. University of California Office of the General Counsel Memorandum, "University Self-Insurance Coverage of Community Members on the IRB", April 8, 1994.
  - 14. UCLA Assistant Vice Chancellor Biomedical Affairs Memorandum, "IRB Indemnity", September 19, 1995.
  - 15. OPRS memorandum regarding oral history and human subjects research [G-IRB Members only]
  - 16. Executive Vice Chancellor Wyatt R. Hume's October 2001 memorandum regarding informed consent procedures for screening activities
  - 17. UCLA research guidelines regarding HIPAA compliance

18. Vice Chancellor Daniel Neuman's November 2002 memorandum regarding surrogate or proxy informed consent
  19. UCLA Guidelines and Procedures for Proxy/Surrogate Informed Consent
  20. Expedited IRB review categories
  21. OHRP guidance on continuing review
  22. OHRP guidance on engagement of institutions in research
  23. OHRP guidance on AIDS research
  24. OHRP guidance on Certificates of Confidentiality
  25. NIH's frequently asked questions regarding Certificates of Confidentiality
  26. OHRP guidance on repositories
  27. OHRP guidance on exculpatory language in informed consent forms
- B. New staff members are given a binder containing OPRS/IRB Policies and Procedures.
- C. New staff members receive hands-on training on the IRB process, human subjects regulations and ethical principles from experienced staff members.
- D. All staff members are required to complete UCLA's Protecting Human Research Subjects (PHRS) education course and HIPAA Clinical Research Training Course.

### **III. Continuing Education of IRB Staff**

- A. Continuing training and education is provided on a daily basis through discussions of regulatory and ethical issues that arise during the processing of research proposals.
- B. Staff members are regularly provided detailed oral and written feedback regarding the clarity of the information provided to investigators and proper documentation of federal regulations and ethical principles.
- C. Staff members are expected to attend all scheduled staff meetings, which are held on a regular basis and may include all staff, medical staff only, social behavioral staff only, all of the staff members who support an individual IRB, or staff within the same job classification.
- D. Staff members are expected to attend training sessions which are conducted on an on-going basis on specific topics.
- E. Staff members are expected to sign up for the *Human Research News* e-mail listserv so that they receive the same notifications as the rest of the UCLA research community.
- F. Staff members are encouraged to read the IRB Discussion Forum, which promotes the discussion of ethical, regulatory and policy concerns with human subjects research.
- G. Each staff member is provided a copy of the journal *IRB: Ethics and Human Research*.

- H. Copies of the textbook *Institutional Review Board: Management and Function* and other reference materials related to research ethics are available for reference.
- I. The Director, Assistant Directors and Administrators attend national and regional conferences on the protection of human research subjects. Conference expenses are covered by the OPRS. Conference attendees are expected to present information gained to other IRB staff.

#### **IV. Evaluation of IRB Staff**

Staff are evaluated daily on their ability to analyze and articulate committee decisions and investigator inquiries. On an annual basis, all staff members receive a formal evaluation and are provided extensive feedback regarding their performance. Supervisors use the UCLA Employee Performance Evaluation Form to conduct the performance appraisal.

#### **References:**

UCLA's Protecting Human Research Subjects (PHRS) education course:  
<http://www.training.ucla.edu/ucla/>

#### **Attachments:**

OPRS-14      UCLA IRB/OPRS Staff Job Descriptions