

Policy Number: 49

Title: Education and Training of IRB Members

Date of Last Revision: 01/21/07, 10/29/10, 01/28/15

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all IRB Committee members complete initial and periodically training in the review and conduct of human research protections.

- I. All new Committee members are required to complete an initial orientation before being assigned as a reviewer. Initial orientation includes:
 - A. An educational session with an IRB Administrator detailing: the UCI IRB policies and procedures, The Belmont Report, Federal regulations 45 CFR 46, 21 CFR 50 and 56, and other applicable regulations and guidance, including Department of Defense (DoD) requirements.
 - B. IRB members receive the following materials prior to attending their first IRB meeting:
 1. Original signed copy of the IRB member appointment letter;
 2. IRB Member Standards letter for signature
 3. Conflict of Interest (COI) Disclosure Form (Biomedical IRB Members only)
 4. IRB Member Questionnaire;
 5. Schedule of Committee meetings and IRB submission deadlines;
 6. Roster for respective IRB Committee;
 7. IRB Member Resource e-mail, containing the following materials or links to the following:
 - a) The Nuremberg Code;
 - b) World Medical Association Declaration of Helsinki;
 - c) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects;
 - d) Exempt and Expedited Categories;
 - e) 45 CFR part 46;
 - f) 21 CFR 312 and 812;
 - g) California State Statutes applicable to Human Subjects Protections;
 - h) UCI Human Research Protections- Standard Policies and Procedures;
 - i) IRB Reviewer Checklists for Exempt, New and, Continuing review;
 - j) IRB Reviewer Checklist for Informed Consent Process; and
 - k) IRB Reviewer Supplemental Checklists for Vulnerable Subject Populations.
 - C. In addition, to the above materials, each new biomedical IRB Committee member receives the manual entitled "Regulations and Guidance on the Protection of Human Subjects: Clinical Investigators, IRB and Sponsor Responsibilities" which includes:
 - a) The Common Rule: Title 45 CFR part 46;
 - b) 21 CFR parts 11, 50, 54 and 56;
 - c) FDA Information Sheet Guidance;
 - d) FDA Bioresearch Monitoring Compliance Program;
 - e) OHRP Guidance on Unanticipated Problems and Adverse Events and
 - f) DHHS Guidance on HIPAA Privacy in Research.
 - D. Collaborative IRB Training Initiative (CITI) Basic Human Research Protections Course for IRB Members - All IRB members are required to complete this tutorial within 3 months of

their appointment. UCI offers two versions of the Basic Human Research Training course: one for Biomedical IRB members and one for Social & Behavioral IRB members. A refresher course is required every five years for members to maintain their knowledge of ethical considerations and regulations regarding human research protections. For IRB members, the tutorial includes:

1. The historical event and ethical principles, associated with the conduct of research with human participants;
2. The definition of research with human participants and the federal regulations;
3. The informed consent process;
4. Vulnerable populations;
5. Food and Drug Administration (FDA) considerations;
6. Department of Defense (DOD) applicability;
7. IRB regulations and the IRB review process;
8. Additional training on the role of an IRB member is provided.

E. Health Insurance Portability and Accountability Act (HIPAA) Research Tutorial – The internet-based tutorial developed by the UC is designed specifically for researchers involved with Protected (Personal) Health Information (PHI). All IRB members are required to complete the HIPAA Research tutorial within 3 months of their appointment. The learning objectives of the HIPAA Research Tutorial are:

1. To provide a general introduction to the HIPAA regulations and define what constitutes Protected Health Information; and
2. To provide a clear understanding of how HIPAA applies to research involving humans.

F. Committee Meeting Attendance and Observations – In addition to completing the initial orientation, new IRB Committee members must attend and observe at least one IRB Committee meeting before being assigned as a reviewer.

II. All IRB members are provided with the training and materials necessary to determine whether a human research study is in compliance with Federal regulations, applicable State laws, UC/UCI policies, DoD requirements and standards of professional/ethical conduct and practice.

A. The following opportunities for training are provided to all IRB members:

1. Provision of Materials and Presentations during IRB Service: The HRP staff regularly provides IRB members with relevant educational materials (e.g., sections of the OHRP guidebook), articles and updates to Federal regulations, State laws and UC/UCI policies. In-service educational presentations by the HRP staff are also provided during IRB meetings on an as needed basis.
2. IRB Membership Training: IRB training is offered on an individual basis or on an as needed basis by the HRP staff. The goal is to keep members up-to-date on Federal regulations, State laws and UC/UCI policies. The IRB members are also given an opportunity to ask questions and to receive assistance by the HRP staff. Group Training is also periodically provided to IRB members by the HRP staff.
3. Conferences/External Meetings: The IRB Chair and/or at least one Committee member for each Committee are encouraged to attend a national or regional human research protections conference annually.
4. ORA Human Research Protections Website: The HRP website provides public access to IRB guidelines (e.g., difference between exempt, expedited and full committee research, requirements of informed consent, special considerations for vulnerable subject populations, etc.), principles of human subject protection (e.g., the Belmont Report, Nuremberg Code and Declaration of Helsinki), Federal regulations, State statutes, DoD requirements related to human subject research, UC/UCI policies and UCI procedures. The website also contains a customized web page especially

for IRB members, which includes links to frequently used information, PowerPoint presentations on IRB topics, links to Office for Human Research Protections (OHRP) videos and other relevant postings that assist IRB members in their role.

References:

UC Irvine Human Research Protections website: <http://www.research.uci.edu/ora/hrpp/index.htm>
[DoD: DoDD 3216.2, para 4.5, SECNAVINST 3900.39D para. 6a\(2\)](#)

Procedure Number: 49.A

Title: Procedure for Education and Training of IRB Members

Procedure:

This procedure outlines the process for completing the human research protections educational requirements for the UC Irvine (UCI) Institutional Review Board (IRB) Committee Member.

I. IRB Committee Member Responsibilities

- A. All IRB Committee members must complete the CITI Basic Human Research Protections Course for IRB Members and the HIPAA Tutorial, prior to being assigned as a reviewer. All tutorials must be completed within 3 months of appointment.
- B. New IRB Committee members must attend and observe at least one IRB committee meeting prior to before being assigned as a reviewer.
- C. IRB members should review the training and educational materials provided by the HRP staff. These materials aid members in determining whether a human research study is in compliance with Federal regulations, applicable State laws, UC/ UCI policies, DoD requirements and standards of professional/ethical conduct and practice.
- D. IRB members should review the educational resources presented at the IRB Committee meetings.

II. IRB Management and Administrator Responsibilities

- A. The IRB Education and Quality Improvement Team are responsible for:
 - 1. Developing the new Committee member's orientation session;
 - 2. Maintaining Committee member education documentation;
 - 3. Planning and executing monthly education at the IRB Committee meetings; and
 - 4. Planning and executing the periodic training for IRB Committee members.

III. IRB Administrator Responsibilities

- A. The Administrator will assure the Committee member has completed all initial and continuing education requirements as outlined in IRB Policy 49.
- B. The Administrator is responsible for scheduling and conducting the new Committee member's orientation session.