Policy Number: 48
Title: Education and Training of Lead Researchers and Research Personnel
Date of Last Revision: 08/10/05, 05/26/10, 10/29/10, 01/21/10, 01/28/15, 01/01/17, 05/30/18, 08/21/18, 09/16/22

Policy:
It is the policy of the UC Irvine (UCI) to promote the highest ethical standards in the conduct of research. Lead Researchers and research personnel conducting human subjects research under the jurisdiction of the UCI IRB must complete education and training regarding the protection of human subjects in research. These requirements are designed to ensure that investigators have appropriate knowledge of human subject regulations and procedures, and that they understand the ethical considerations underlying human research protections.

I. All UCI faculty, staff, and students who serve as lead researchers, co-researchers, or research personnel on a human research study, regardless of the funding source must complete UCI education requirements and provide certification of completion to the UCI IRB.

II. Faculty sponsors who provide direct oversight of human subjects research must also meet UCI human research protection educational requirement.

III. Educational Requirements:

A. Human Research Tutorials – For individuals engaged in human subject research Human Research Protections (HRP) offers two self-paced, web-based tutorials as follows:

1. The Collaborative IRB Training Initiative (CITI) Basic Human Research Protections course (for Biomedical Investigators and for Social & Behavioral Investigators); and
2. The CITI Research and HIPAA Privacy Protections course.

Individuals choose the course that best matches their research activities. These tutorials review core concepts for the responsible conduct of research involving human subjects and guide users through the major principles for conducting research in a way that is consistent with federal and University requirements and with accepted scientific standards. Completion of the tutorials is required of individuals (i.e., Lead Researcher, Co-Investigators, Research Personnel and Faculty Sponsors) who wish to engage in human subject research at UCI before submission of IRB documentation. Additional optional modules are offered via CITI as well.

B. The learning objectives of the CITI Human Research Protections Training course are:

1. To provide an understanding of the historical perspectives, ethical principles, associated with the conduct of research with human participants;
2. To provide a general introduction to the federal regulations and define what constitutes research with human participants; and
3. To provide a clear understanding of what constitutes informed consent and how it must be applied in research involving humans.

C. The Collaborative IRB Training Initiative (CITI) Human Research Protections Training course – Refresher course – Lead researchers, co-researchers, faculty sponsors and research personnel are required to complete a CITI refresher course every five years to maintain their knowledge of ethical considerations and regulations regarding human research protections.

1. New researchers who have not completed the Human Research tutorial must complete the CITI basic training for either biomedical or social/behavioral research.
2. Researchers who have completed the HR tutorial in the last five years must complete the applicable CITI refresher training before their five-year anniversary.
3. Researchers who have completed a CITI basic training at another institution must access the CITI training program and add UCI as a "Participating Institution" in the CITI Course Registration section and complete applicable CITI refresher courses.
4. Researchers will receive 90 day notification prior to their five year anniversary of completion of the HR tutorial or CITI training – basic or refresher.

D. The CITI Research and HIPAA Privacy Protections course discusses the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and how they supplement the U.S. Department of Health and Human Services (HHS) and U.S. FDA requirements. It also describes situations where full HIPAA privacy protections are required and those that can qualify for waivers, alterations or exemptions with more limited requirements. In addition, it reviews the responsibilities of researchers and institutions for meeting HIPAA privacy requirements and for appropriate data security protections that are necessary to protect privacy.

1. All Researcher and research personnel involved in studies that access, create or disclose Protected Heath Information (PHI) must complete the tutorial.
2. As of July 5, 2017 the CITI Research and HIPAA Privacy Protections course was incorporated as a requirement for all Biomedical Investigators and it was made available to Social & Behavioral Investigators as an optional course.

E. Good Clinical Practice (GCP) Training for National Institutes of Health (NIH) Research: On September 16, 2016, the NIH issued a new policy that specifies NIH-funded investigators and staff should be trained in GCP. The NIH policy states that all NIH-funded investigators and staff "who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2)."

1. HRP offers several CITI courses that meet the NIH requirement.
2. A refresher course should be completed every three years.

IV. Lead researchers, co-researchers, faculty sponsors and research personnel who do not complete the requisite Human Research Protections requirements within the required timeframe may be restricted from engaging in research involving human subjects until the requirements are met.

V. In addition to completing the UCI HRP education requirements noted above, for research involving the Department of Defense (DoD), all personnel who conduct, review, approve, oversee, support, or manage human participant research must *also* meet DoD requirements for research ethics training (see Policy 56). DoD requirements are also posted at the Human Research Protections Program (HRP) website.

VI. The Human Research Protections (HRP) website has been created as a resource for all researchers. The website will assist the researchers in navigating the IRB process and adhering to the Federal regulations and IRB policies related to human research protections.

VII. All investigators and research personnel conducting research involving humans at UCI are encouraged to review the core training materials including the UCI Federalwide Assurance, the UCI IRB policies and procedures, *The Belmont Report*, the Federal regulations including 45 CFR 46, 21 CFR 50 and 56, links to Federal agencies governing human subjects research, and links to other various agencies and resources (e.g., National Institutes of Health, Food and Drug Administration, Office of Human Research Protections, National Bioethics Committee, DoD, etc.) These links are available on the HRP website.

VIII. The HRP sends e-mail notifications (i.e., Zotmail) to a mailing list of researchers and key study personnel subscribers, to alert them of pertinent IRB issues or decisions that may impact their research. Zotmail messages are then archived and can be accessed via the HRP website.

IX. Office for Human Research Protections (OHRP) Video Presentations. The HRP website will maintain educational videos developed by the Division of Education and Development at OHRP. Videos provide information on a variety of topics related to the regulations for the protection of human subjects of research described at 45 CFR Part 46. These videos will be posted for the purpose of educating researchers. Each video is approximately 20-25 minutes in length.

X. IRB Brochure: “Institutional Review Board – Fast Facts” This brochure targets investigators and research personnel to provide basic information about the IRB process including:
   (1) The role of the IRB;
   (2) Definition of research, human subject, and clinical investigation;
   (3) Requirements for conducting research involving humans at UCI;
   (4) UCI IRB Review Process
   (5) Types of IRB review; and
   (6) Resources for additional information.

XI. New researchers, research personnel, and graduate students may request an in-service or “Office Hours” with HRP Staff for the purpose of providing an overview of human research subject regulations and IRB requirements. On-site “Office Hours” are offered by HRP Staff in response to specific requests by the research community regarding human subject research queries. Appointments may be scheduled by emailing HRP Staff.

References:

UC Irvine Human Research Protections Program website:
https://research.uci.edu/human-research-protections/
Department of Defense Human Research Protections Program website:
https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/
Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials; NOT-OD-16-148

Procedure Number: 48.A
Title: Procedure for Education and Training of Lead Researchers and Research Personnel

Procedure:
This procedure defines the process of meeting the educational requirements for Lead Researchers and research personnel conducting research involving humans under the jurisdiction of the UC Irvine (UCI) Institutional Review Board (IRB).

II. **Lead Researcher (LR) and Research Personnel Responsibilities**

A. Initial Training - All Lead Researchers, co-researchers, faculty sponsors and research personnel must complete the Human Research tutorial and HIPAA Research tutorial, if applicable.

1. Effective September 10, 2018: The Lead Researcher will be responsible for confirming that applicable CITI educational tutorials have been completed for UCI undergraduate students serving as research personnel on minimal risk protocols conducted within the state of California. A research personnel log may be used for such purpose. A Human Research Protections (HRP) Research Personnel Log template has been created and is available on the Applications and Forms page: https://research.uci.edu/wp-content/uploads/study-team-tracking-log.xlsx.. Tutorials may be verified using the Tutorial Verification Search.

B. The LR will utilize the HRP website to navigate through the IRB process and adhere to the Federal regulations and IRB policies related to human research protections. Additionally, the LR will access the HRP website to view various educational resources. The URL for the HRP website is https://research.uci.edu/human-research-protections/.

C. All Lead researchers, co-researchers, faculty sponsors and research personnel will keep up to date on current events and review the HRP website for current IRB policies and procedures and the Federal regulations, especially those applicable to their area of research. The website includes the following:

1. UCI's Federalwide Assurance;
2. The IRB Review Process;
3. The HRP Staff Contact List;
4. IRB Forms including the Informed Consent Templates;
5. IRB Policies and Procedures;
6. IRB Roles and Responsibilities;
7. Links to various Agencies and Resources on the IRB website:
   a) National Institutes of Health;
   b) Food and Drug Administration;
   c) Office for Human Research Protections; and
   d) National Bioethics Committee
   e) Department of Defense (DoD) Requirements

D. All Lead researchers, co-researchers, faculty sponsors and research personnel are encouraged to view the various educational tools offered on the HRP website and other opportunities offered by UCI throughout the year.

E. The HRP Education and Quality Improvement Program (EQUIP) as directed by the IRB Committees may provide individualized education to research Investigators and/or their staff in response to deficiencies identified by the Committee. In addition, EQUIP may provide human research protections training at the department's or LR's request.

F. Other resources are available to Investigators and key study personnel. Researchers and study personnel may access all of the following (including all current and prior versions of the following) via the HRP website.

1. IRB Brochure: "Institutional Review Board – Fast Facts" This brochure targets investigators and research personnel to provide basic information about the IRB process.
2. Zotmail: The HRP will send e-mail notifications (i.e., Zotmail) to a mailing list of researchers and key study personnel subscribers, to alert them of pertinent IRB issues or decisions that may impact their research. Zotmail messages are archived as a resource for the research community.
3. OHRP Video Presentations: These educational videos provide information on a variety of topics related to the regulations for the protection of human subjects of research described at 45 CFR part 46.
4. In- Service or Office Hours: New researchers, research personnel, and graduate students may request an in-service or "Office Hours" with HRP Staff for the purpose of providing an overview of human research subject regulations and IRB requirements. On-site "Office Hours" are offered by HRP Staff in response to specific requests by the research community regarding human subject research queries. These sessions may be scheduled by contacting HRP Staff via email or phone. Contact information for all HRP Staff is maintained on the HRP website.

H. The Investigator will keep all IRB applications current with Investigator and key study personnel contact information to facilitate the receipt of all mass e-mail notifications alerting them of pertinent IRB issues or decisions that may impact their research.

III. HRP Responsibilities

A. The HRP will conduct educational sessions throughout the year for all UCI faculty and staff.
   1. An example is the quarterly research administration meeting (QRAM).

B. The HRP will maintain its website with links to Federal, State and institutional resources.

C. The HRP Staff will maintain active links to the CITI educational tutorials via the website. In addition, current CITI status is provided for the LR and all study team members via the online IRB submission and management system.

D. The HRP staff is available Monday through Friday 8:00 a.m. – 5:00 p.m. to answer questions and assist lead researchers, co-researchers, faculty sponsors and research personnel with any educational needs.