

**Institutional Review Board  
IRB Education Policy and Procedure**

**Effective: October 19, 2015**

**Revised: May 25, 2016**

**Version: 1**

**Responsibility: OIRB**

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**Policy**

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- A. All IRB members and chairs must complete appropriate education in research ethics, human research protections, IRB responsibilities and regulatory policy.
- B. All IRB and OCR Office staff must complete appropriate education in human research protections and regulatory policy.
- C. The Institutional Official must complete appropriate education in human research protections and institutional responsibilities under the federalwide assurance.
- D. Alternate research ethics training may be considered in lieu of CITI training on a case by case basis.

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**Overview**

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- A. This policy addresses requirements for Research Ethics training for the following groups:
  - 1. IRB Members and IRB Chairs
  - 2. Office of the Institutional Review Board (OIRB) staff and Office of Clinical Research (OCR) staff
  - 3. Institutional Official/Alternate Institutional Official

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**Procedure**

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- A. IRB members and chairs

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1. IRB members and chairs must complete the HSC IRB Member education within three months of being appointed to the board.
  - a) The HSC IRB Member training is hosted on the University of Miami's Collaborative Institutional Training Initiative ([CITI](#)) website. The modules as part of this learner group involve information about the ethical principles of research, IRB regulations and review, informed consent, research with vulnerable populations, etc.
  - b) The IRB Member training must be renewed every three years by completing the refresher course.
  - c) The OIRB staff use the OIRB database to monitor IRB member training and provide regular reports to the members, chair and IRB Director of training status and impending expiration dates. If training lapses for extended periods, the chair and IRB Director will take this into account when providing annual member feedback and member re-appointments.
  - d) Orientation of new IRB Members - following appointment as a member on the IRB and prior to serving as reviewers (primary or secondary), IRB members, ex officio members, and alternate members receive the following training:
    - (1) The OIRB staff provides new and existing members with a general orientation. Following the annual assignment of members, the OIRB provides an orientation session for all new and current board members.
    - (2) As new members are added to the board throughout the year, they will meet with the IRB Chair or designee to review roles and responsibilities either one-on-one or in a small group.
  - e) Existing members may request one-on-one trainings or attend scheduled small group trainings as needed.
  - f) IRB members are provided with continuing education as part of most meeting's standard agenda. The education topic is generally selected to coincide with an issue from one of the studies scheduled for review at the meeting.
  - g) Additional educational materials containing ethical and regulatory guidance for the review of protocols involving a specialized area, (i.e., gene therapy or tissue banking) or selected vulnerable subject populations (i.e., prisoners) are provided specifically to primary/secondary reviewer or to all members as appropriate.
  - h) The OIRB provides funding for the Chairs, members and/or regulatory specialists to attend national continuing education conferences, as budgets permit.
- B. The Office of the IRB (OIRB) and Office of Clinical Research staff
  1. The staff must complete the HSC IRB Member education and Good Clinical Practices (GCP) Curriculum within three months of being employed in the OIRB/OCR. Staff who hold and maintain a CIP (Certified IRB Professional) certification, are exempt from the requirement to complete the CITI training and GCP curricula.

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2. The staff must renew the HSC IRB Member education every three years or maintain current CIP certification.
  3. The staff must complete individualized on-the-job training and orientation as determined by their job description. New staff must review all existing departmental policies and procedures.
  4. The staff is provided with continuing education during regularly scheduled staff meetings (at least monthly). The education topic is generally selected to coincide with an issue from one of the studies scheduled for review at the meeting or related to a recent issue or problem.
  5. The OIRB subscribes to the Hastings Center's IRB Ethics and Human Research which is circulated to the staff.
  6. The Managers track training status of their staff.
- C. The Institutional Official (IO)
1. The IO/alternate IO must complete all three training models provided in the Office for Human Research Protection's (OHRP) "[Human Subject Assurance Training](#)" within three months of being designated as the IO/alternate IO.
- D. Alternate Training Options
1. The IRB Director or IRB Associate Director may determine that other research or ethical education programs (e.g., PRIM&R or FDA sponsored conferences, clinical research academic degree programs), or certifications (e.g., CIP, CRA) may count toward fulfilling minimum training or refresher requirements (for example, if community members have minimal involvement in minimal risk research other forms of ethics training may be acceptable).
  2. Documentation should be submitted to the OIRB by the trained individual as necessary to indicate that training was completed (or refresher training was completed at least once every three years).
  3. Documentation indicating that the IRB Director or IRB Associate Director determined the education to be appropriate education in research ethics, human research protections and regulatory policy should also be maintained by the Research Regulatory Reviewer.

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**References**

Definitions (see [Glossary](#))

Regulatory (see [Policy on Policies Policy and Procedure](#))