3 Education & Training

3.1 Training / Ongoing Education of IRB Chair, Members, and Staff

Recognizing that a vital component of a comprehensive human research protection program is an education program, University of Virginia is committed to providing training and an on-going educational process for IRB members and the staff of the IRB and HRPP Office, related to ethical concerns and regulatory and organizational requirements for the protection of human subjects.

Orientation

New IRB members, including alternate members will meet with the IRB Chair, IRB Staff or Director of the HRPP Office for an informal orientation session. At the session, the federal regulations will be reviewed and an orientation to IRB processes and on-line materials will be given. Online resources include, but are not limited to:

- Belmont Report;
- University of Virginia HRPP Standard Operating Procedures;
- Federal regulations relevant to the IRB;
- Tools used by IRB reviewers (checklists etc.).

Also, the new member will be given an Institutional Review Board Member Handbook .

New members are required to complete the Initial Education requirement for IRB members before they may serve as Primary Reviewer.

Initial Education

IRB members and HRPPIRB staff will complete the required modules in the CITI Course in the Protection of Human Research Subjects (biomedical or social behavioral track, as applicable), including the IRB Member Module - "What Every New IRB Member Needs to Know" and the module on Conflicts of Interest. Community members are expected to review the "I Have Agreed to be an IRB Community Member. Now What?" module as well.

Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB is consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB.

In addition to initial training requirements, IRB members and HRPP and IRB administrators and staff must also satisfy continuing education requirements on an annual basis. University of Virginia uses the following activities as a means for offering continuing education to IRB members and HRPP and IRB administrators and staff:

- In-service training at IRB meetings;

- Conference attendance;
- Copies of appropriate publications;
- Identification and dissemination by the Director of new information that might affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings; and
- Unlimited access to the IRB Office resource library.

IRB members and HRPP and IRB staff are also required to complete CITI training every 3 years as part of the University of Virginia continuing education requirements.

The activities for continuing education vary on a yearly basis depending on operating budget and areas of need, as determined by the IRB Directors. The IRB Directors determine which continuing education activities are mandatory for IRB members and staff in a given year. The IRB Directors or designees track whether each individual has satisfied the requirements. IRB members who have not fulfilled their continuing education requirements will not be assigned as primary or secondary reviewer until they are fulfilled. Continuing failure to complete training may result in the individual being removed or not renewed as an IRB member. Fulfillment of training requirements is included as part of the evaluation of the performance of IRB members/alternates.

Members and staff who are unable to attend education sessions will be provided with the opportunity to make-up any training that they missed. If a make-up session is not possible (e.g., a webinar or conference), then an equivalent educational opportunity will be offered at the discretion of the Director.

The Institutional Official (IO) will provide support to send as many members of the IRB as possible to attend the annual PRIM&R conference, the Virginia IRB Consortium Conference or regional conferences on human research protections.

3.2 Training / Ongoing Education of Investigators and Research Team

As stated previously, a vital component of a comprehensive human research protection program is an education program for all individuals involved with research subjects. The University of Virginia is committed to providing training and an on-going educational process for investigators and members of their research team related to ethical concerns and regulatory and organizational requirements for the protection of human subjects.

3.2.1 Initial Education

Investigators, key personnel, and other members of the research team must complete University of Virginia required core modules in the CITI Course in the Protection of Human Research Subjects including the module on Conflicts of Interest. Evidence of current training (date of completion within 3 years of application date) for each member of the research team

must be included in every new research study application and application for continuing review.

New research plans and applications for continuing review will not be approved from investigators who have not completed the initial education requirement.

While research plans and applications for continuing review will be accepted and reviewed if the investigator holds a current certification of training, final approval will not be granted until all co-investigators and members of the research team have completed the initial education requirement.

Waiver of Initial Education

If individuals can provide documentation verifying that they have successfully completed human subject research training equivalent to that required by the University of Virginia, they may request a waiver of the requirement for Initial Education. IRB staff will review the documentation and determine if it satisfies organizational standards. However, all investigators or members of their research team must complete the requirements of Continuing Education as reviewed below.

3.2.2 Continuing Education and Recertification

Investigators, key personnel, and other members of the research team must meet the University of Virginia continuing education requirement every [three (3)] years after certification of Initial Education for as long as they are involved in human subject research. There is no exception to this requirement. Acceptable training includes attendance at approved PRIM&R, OHRP, or FDA seminars and conferences, attendance at HRPP Human Subject Research Presentations, or review of appropriate refresher modules at the CITI web-based training site. Other training may be acceptable. In these cases the investigator should check with the IRB Office for a determination.

Individuals must submit to the IRB office evidence of continuing education prior to the expiration of their training certification. New research plans and applications for continuing review will not be accepted from investigators who have not submitted satisfactory evidence of continuing education.

Investigators who are also IRB Chair, IRB members, or IRB Office staff will satisfy the training requirements for IRB members and staff described in this policy under Section 3.1.