Title:	Education & Training		
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1 Purpose

Recognizing that a vital component of a comprehensive human research protection program is an education program for all individuals involved with research subjects, the University of North Carolina at Chapel Hill (UNC-Chapel Hill) is committed to providing training and an on-going educational process for IRB members, the staff of the IRB and HRPP Office, investigators and members of their research team, related to ethical concerns and regulatory and organizational requirements for the protection of human subjects.

2 Procedures

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

2.1.1 Orientation

New IRB members, including alternate members will meet with the Education & Training Manger of the HRPP Office for an informal orientation session when they observe their first IRB meeting. Prior to this orientation meeting, new members are sent a set of 6 PowerPoint Modules that provide an overview of IRB function, ethics, regulations, HIPAA, IRB 111 Review Criteria and operations. New members are also required to complete the PRIM&R on-line course for IRB Members (eROC), or other equivalent, approved research training prior to becoming a voting member. At the orientation session, new members also have a training session with the Data & Information Manager on the electronic IRB program. At orientation the new member will be given an IRB Handbook, Amdur & Bankert, 3rd Edition and an encrypted flash drive that includes:

- Belmont Report;
- Nuremburg Code
- Helsinki Declaration
- TriCouncil Ethical Conduct
- 2002 CIOMS International Ethical
- 2011WHO Standards & Operational Guide
- E6 Guideline
- OHRP 2016 International Compilation of Human Research Standards

- OHRP Informed Consent Checklist
- Past IRB Meeting Educational Presentations
- 1963 Milgram Behavioral Study
- 1966 Beecher “Ethics & Clinical Research”
- 1972 Heller Syphillis Victims
- 1986 Krugman Willowbrook
- 1966 Faden Advisory Committee
- 2001 Gelsinger, “Jesse’s Intent”
- 2010 Physicians Experiments in Torture
- 2011 Reverby Normal Exposure
- Consent templates
- Social Security Number Disclosure, use for research and use as an identifier
- The UNC-Chapel Hill Policies and Procedures for the Protection of Human Subjects;
- Federal regulations relevant to the IRB; and
- Tools used by IRB reviewers (checklists etc.).

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

2.1.2 Initial CITI Education

IRB members and HRPP and IRB administrators and staff will complete the required modules in the CITI Course in the Protection of Human Research Subjects. The modules are grouped by categories of research. Researchers, IRB Members & Staff are only required to complete one group of modules that best fits the type of research they normally conduct.

- **Group 1:** Biomedical Research: Medical, physiological or pharmacological studies that typically involve direct contact with subjects. Includes, but is not limited to, research with drugs, devices or other interventions.
- **Group 2:** Social and Behavioral Research: Studies on sociological, psychological, anthropological or educational phenomena that typically involve direct contact with subjects. Does not include drug or device studies.
- **Group 3:** Data and Specimens ONLY: No direct contact with human subjects. Research limited to use of records, data (including secondary data sets), or biological samples.

2.1.3 Continuing Education for IRB Members

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. The UNC-Chapel Hill uses the following activities as a means for offering continuing education to IRB members and HRPP and IRB administrators and staff:

- Annual IRB Member Retreat
- IRB Meeting 10-minute educational presentations which are mailed to every IRB Member and senior staff each month and are also posted on a members' webpage
- Monthly email to all IRB Members & Analysts of the meeting in-service materials and additional regulatory updates, recent publications and guidance.
- A Member & Staff website that includes copies of education handouts, dates of upcoming educational offerings of interest to members & staff; links to other training resources; references from governmental sites (OHRP, FDA, NIH, DOE, EPA); educational offerings from OHRP and other IRBs; a membership directory; a link to CITI; AAHRPP and topical informational sites (FDA Drugs; Medline Plus tutorials; Certificates of Confidentiality).
- Periodic webinar offerings
- Monthly sessions with the IRB Analysts
- Monthly sessions with IRB non-scientist and unaffiliated members
- 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.

The activities for continuing education vary on a yearly basis depending on operating budget and areas of need, as determined by the Education & Training Manager in consultation with the OHRE Director. The Education & Training Manager tracks 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. The Institutional Official (IO) will provide support to send as many members of the IRB as possible to attend the annual PRIM&R conference or regional OHRP conferences on human research protections.

2.2 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 UNC-Chapel Hill 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.

2.2.1 Initial Education

Investigators, key personnel, and other members of the research team must complete the UNC-Chapel Hill required core modules in the CITI Course in the Protection of Human Research Subjects including the module on Conflicts of Interest. Evidence of training for each member of the research team must be documented for 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.

2.2.1.1 Documentation of Equivalent Education

If individuals can provide documentation verifying that they have successfully completed human subject research training equivalent to that required by the UNC-Chapel Hill they may request a substitution of the requirement for Initial Education. The OHRE Director or designee will review the documentation and determine if it satisfies organizational standards.

2.2.1.2 Continuing Research Ethics Education Requirements

Continuing education requirements in the Protection of Human Research Subjects (as described above) must be completed at least every 3 years. Continuing education is tracked by the electronic IRB system. Final approval of initial and continuing review will not be granted until all appropriate members of the research team have completed the designated CITI refresher course.

2.2.2 Additional Educational Opportunities

The Education & Training Manger and other IRB Staff make a number of presentations throughout the UNC CH campus. These presentations include:

- Requests from study teams for additional training,
- Requests for class presentations on IRB Overview as part of an undergraduate or graduate level class,
- Requests to lead research ethics seminars for residents,

- Twice a year an IRB Overview is presented by IRB staff in the orientation series of lectures for new study coordinators.