1.23 HRPP Training Requirements

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements and opportunities for training for all personnel involved in conducting human subject research.

2.0 Policy

It is the policy of the Organization that all personnel involved in the conduct of human subject research under the oversight of the UNMC IRB will be qualified through initial and continuing education in order to fulfill their responsibility to protect the rights and welfare of human subjects.

3.0 Definitions

- **3.1.** Biomedical Research is defined (as per HRPP policy 1.8 Investigational Activities Requiring IRB Review & Approval, section 4.1) as research performed with intent to develop or contribute to generalizable knowledge (i.e., test a hypothesis and draw conclusions) about human biological systems and processes, including efficacy and safety of preventative, diagnostic or therapeutic methods. Biomedical research includes:
  - **3.1.1.** Clinical trial using a drug, medical device, technique or other intervention or strategy (including non-physical means, like diet, cognitive therapy, etc.) to diagnose, treat or otherwise study a particular condition or disease
  - **3.1.2.** Non-clinical biomedical research to study normal or abnormal physical or physiologic processes (for example, gait and balance testing, biomechanical assessments).For the purpose of this policy “Biomedical Research” includes Human Biological Material Research and Medical Records Research (per HRPP policy 1.8 Investigational Activities Requiring IRB Review & Approval, sections 4.2 and 4.3 respectively)
- **3.2.** Social Science and Behavioral Research is defined (as per HRPP policy 1.8 Investigational Activities Requiring IRB Review & Approval, section 4.4) as research performed with intent to study behaviors, attitudes and interactions and social processes among and between individuals, groups, and cultures. Generally this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the subject who is not seeking nor expecting a health benefit from the research.

4.0 Required Training

- **4.1.** Collaborative Institutional Training Initiative (CITI)
  - **4.1.1.** Training in the protection of human subjects is primarily accomplished through completion of this web-based training program. CITI training is required for:
    - **4.1.1.1.** All investigators and research staff conducting non-exempt research who (a) participate in the process of consent, (b) have contact with subjects, or (c) have access to identifiable private information or identifiable biospecimens.
    - **4.1.1.2.** Faculty Advisors of student investigators.
  - **4.1.2.** The CITI Training Program is accessible via http://www.citiprogram.org, or through a link on the UNMC IRB website.
  - **4.1.3.** The Biomedical and the Behavioral and Social Science courses consist of a series of Basic (core) modules which must be completed by users, and additional modules (primarily related to specific types of research or research subject populations). The GCP course consists of a series of required modules.
  - **4.1.4.** CITI training course requirements
    - **4.1.4.1.** The Biomedical course must be completed by personnel described in section 4.1.1 who conduct non-exempt biomedical research (including medical records and human biological material {HBM}) within the Organization or at external sites where the UNMC IRB serves as the IRB of record.
    - **4.1.4.2.** The Behavioral and Social Science course must be completed by personnel described in section 4.1.1 who conduct non-exempt Behavioral and Social Science research within the Organization or at external sites where the UNMC IRB serves as the IRB of record.
    - **4.1.4.3.** The GCP (Good Clinical Practice) course must be completed by:
      - **4.1.4.3.1.** Personnel described in section 4.1.1 who conduct a clinical trial funded by NIH. For the purpose of this policy, “clinical trial” is defined as “a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes” (per NIH Policy NOT-OD-15-015)
      - **4.1.4.3.2.** Personnel described in section 4.1.1 who conduct research utilizing an FDA regulated drug, device or biologic.
  - **4.1.5.** All research personnel must be CITI trained prior to IRB approval of initial research applications.
    - **4.1.5.1.** Personnel described in section 4.1.1 must complete all Basic (core modules) appropriate for the type of research (as per 4.1.3.1 thru 4.1.3.3)
    - **4.1.5.2.** Personnel described in section 4.1.1 who are conducting research where the additional modules are relevant must attest that they have completed those additional modules before final release of the protocol by ORA.
  - **4.1.6.** New research personnel added to IRB-approved research via a Request for Change or Application for Continuing Review must complete CITI training as described above prior to involvement in the research.
  - **4.1.7.** The Organization will accept CITI Training records from other institutions if the other institution utilized the CITI training courses specified above. A copy of any training record must be provided to the ORA.

    - **4.1.8.** On a case by case basis, the Organization may accept other forms of Human Subject protection, or GCP training, instead of CITI, provided such training is substantively similar, was completed at a site that did not participate in the CITI Program, and has been completed in the previous three years. The Executive Chair, in consultation with the IO as needed, will have the sole authority to accept such training.
    - **4.1.9.** The Organization will accept other certificates of training from external organizations for external research personnel conducting non-exempt biomedical research at external sites where the UNMC IRB is the IRB of record. The PI must certify that all external research personnel have completed appropriate training.
    - **4.1.10.** CITI training (including GCP Training) must be renewed every three years from the original date of completion. Training must be up to date for the individual to be listed on new IRB applications or added to existing IRB-approved applications, in the roles defined in Section 4.1.1. However, personnel already listed on an active protocol whose CITI training expires may continue associated with that protocol.
- **4.2.** Conflict of Interest Training
  Conflict of Interest Training is required in accordance with UNMC Conflict of Interest policy #8010 and HRPP policy 1.25 (Financial Conflicts of Interest).

5.0 Additional (Optional) Training

- **5.1. UNMC Websites**
    - **5.1.1.** The HRPP Policy Manual is posted on the UNMC Guides website. When policies are updated, a Summary of Changes will be included with the HRPP Policy Manual.
    - **5.1.2.** The IRB website contains the links to OHRP, FDA, Office of Civil Rights and other websites where research personnel can access the federal regulations, guidance documents and other information pertinent to human subject research.
    - **5.1.3.** ORA Staff will periodically post access to relevant presentations and other educational materials on the IRB website.
- **5.2. Individual Training**
    - **5.2.1.** The IRB Administrators provide individualized training to any research personnel on request. This training may be conducted in the ORA or at any requested location within the Organization.
    - **5.2.2.** Supervisors of new employees of the Organization may request IRB Introduction and Overview as mandatory training. This training is generally provided by an IRB Administrator.
- **5.3. UNMC IRB Workshops**: Workshops are scheduled on various topics, such as the IRB online submission system, informed consent and how to work more effectively with the IRB. Research personnel within the Organization are notified in advance.
- **5.4. Student Education**: Didactic classroom presentations are offered to UNMC and UNO students on topics pertaining to human subject protection by request.
- **5.5. Webinars**: The ORA facilitates access to webinars sponsored by external organizations on topics relevant to Human Subject Research.
- **5.6. HRPP Regional Conference** (“Hot Topics in the Protection of Human Subjects”): The regional conference, produced in collaboration with the Great Plains Health Research Consortium, and partially funded by the Great Plains IDeA-CTR Network, brings together

national and local speakers to explore cutting edge topics in human research subject protection. The conference has occurred annually since 2010, though postponed in 2020 due to the Coronavirus pandemic. The target audience is IRB administrators and staff, IRB members, investigators and research coordinators.

6.0 Procedures for Assessing Training Requirements

- **6.1.** At regular intervals, the Assistant Vice-Chancellor for Regulatory Affairs, the Executive Chair, the IO and the ORA will re-evaluate the content, specific requirements, and effectiveness of training for research personnel associated with the Organization. This assessment will take into consideration current literature and evolving federal guidance regarding various aspects of research ethics and human subject protection, feedback from research personnel regarding their training needs, assessment of the quality and completeness of IRB submissions by IRB members and the IRB Administrators.

7.0 Procedures for Maintaining Training Records

The ORA maintains all training records for CITI Training and didactic activities described above, and maintains copies of materials sent by mail or email or posted on the website.

DOCUMENT HISTORY:

? Written: 12/28/2015 (Approved: 12/28/2015) - original author not recorded

? Revised: 6/28/2018 - revision not documented

? Revised: 8/31/2021 - Described basic vs additional modules for CITI courses; described requirement to complete additional modules based on type or research and subject population; clarified location of UNMC HRPP Policies manual; correction of references to sections within this and other policies; delineated required vs optional training; deleted training no longer offered; minor stylistic changes and clarification

? Revised: 6/30/2022 - clarification or requirements for CITI biomedical course (section 4.1.4.1) {Approved: 7/2/2022 - Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 8/17/2022 - clarification regarding expiration of CITI training for personnel on an active protocol (section 4.1.10) {Approved - Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/16/2022

Revision #16
Created 21 October 2019 21:51:42 by Autumn M Eberly
Updated 31 August 2023 18:36:27 by Robert A Lewis