IRB Policy 1: Education in the Protection of Human Subjects
Revision Date May 15, 2007, revised January 27, 2011, revised February 9, 2015, revised June 30, 2016, revised May 26, 2017, revised April 2, 2018, revised Feb 7, 2019

I. Pertinent Definitions:

A. Collaborative Institutional Training Initiative (CITI): An internet-based set of human subjects research educational modules administered by the University of Miami. The CITI training modules are designed specifically for all personnel with an involvement in the planning, conduct, and analysis of any scientific activity involving human beings as research subjects.

II. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/ Veterans Affairs Institutional Review Board (ETSU/VA IRB) that all physicians, faculty, staff, or students of the institutions conducting, supervising, or otherwise identified as study personnel engaged in the conduct of human subject research, will be required to complete an ETSU/VA approved course in the ethical conduct of research involving human subjects prior to conducting human subject research. This policy applies additionally to unaffiliated investigators and to investigators submitting research proposals for review and approval to the IRB due to other contractual agreements.

III. Selection of CITI

Ethical principles, professional standards, Good Clinical Practice, policies and procedures, federal regulations and other applicable laws are required education in human subjects protection. IRB members and study personnel, as well as researchers, need training specific to the types of research they review or conduct.

Two learner groups have been established through the CITI program to provide education applicable to the specific knowledge and skills required for different types of research. Those pathways are: ETSU Biomedical and ETSU Social-Behavioral learning groups.

IV. Learning Objectives of CITI

The learning objectives of CITI initial courses are to provide:

- An understanding of the historical perspectives, ethical principles and federal regulations associated with the conduct of research with human subjects.
- A clear understanding of what constitutes human subjects research and how informed consent must be applied in human subjects research.
- Basic information on the regulations and policies governing research with investigational drugs, biologicals, and devices and how the findings of The International Conference on Harmonization affect the conduct of research with human subjects around the world.
- A basic understanding of the risks to privacy and confidentiality of human subjects who participate in social and behavioral research.
- An understanding of the special considerations that must be addressed when "Vulnerable Populations" such as prisoners, minors, pregnant women and fetuses *in utero* are used in research activities.
- An understanding of how to recognize and avoid conflicts of interest in human subjects research.
- New insights into the concept of group harm in vulnerable populations such as minorities and workers in a workplace setting and the use of Community Consultation to prevent injury to special social structures.
- An understanding of the special risks facing human subjects when they participate in research conducted over the internet.
- A clear understanding of the ethical issues and federal regulations in force during the conduct of social and behavioral research, records based research and genetics research with human subjects.
- An understanding of the policies, regulations and risks associated with conducting research with children in public school setting.
- A clear understanding of the special procedural and regulatory policies for human subjects research at VA research facilities.
- New information that may affect the use of human subjects in research. The intent is to provide the user with the latest guidance from regulatory agencies and to provide timely information on new human subjects issues.

V. Documentation of Completion

Completion of required modules identified for each learner group, along with passing scores (overall score of 80% or above), is required for new study staff prior to submitting a proposal for IRB review for approval, regardless of funding or the level of risk associated with the proposal. A period of certification, not to exceed three years, will be awarded.

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CITI training for ETSU/VA human subjects compliance training was initiated in July 2005. Compliance training received at other meetings or institutions will be accepted when the request for approval is received from the investigator in writing along with a course outline and letter or certificate of course completion from the referenced program. Attendance at a national meeting sponsored by Public Responsibility in Medicine and Research (PRIMR) will likewise fulfill the educational requirement. Final determinations will be made by the IRB Chair, Director and/or (for ETSU/VA IRB) the Administrative Officer, VA Research & Development.

VI. Additional VA Guidelines

All individuals who are subject to VA regulation are required to complete training in the ethical principles on which human subject research is to be conducted before they may participate as study staff in human subjects research. Initial testing and re-certification will be verified through the ETSU Office for the Protection of Human Research Subjects (OPHRS) and the VA Research Office. Completion of the CITI VA human subject training on an every 3 year (defined as within 1095 days of the previous training) basis satisfies the VA requirement.

VII. IRB Member Education

Written documentation for course component completion will be required for all IRB members. Information regarding most current compliance education requirements will be posted to http://www.etsu.edu/irb. At minimum, the following will be required of all IRB members:

ETSU and ETSU/VA IRB Members: The CITI Course in the Protection of Human Research Subjects, administered through the University of Miami, is utilized for compliance training beginning in July 2005. New members of the ETSU IRB will be required to complete the ETSU Social-Behavioral Learner Group, and new members of the ETSU/VA IRB will be required to complete the Biomedical Learner Group. VA IRB members are required to take their CITI human subject training through the James H. Quillen VAMC as their learner institution. Training for new IRB members is required within the first thirty days. Educational activities are additionally provided for IRB members at convened meetings.

The IRB Chairs, Institutional signatory officials, and the Human Subjects Protection Officer are additionally required to complete all three Office for Human Research Protections (OHRP) training modules for assurances.

VIII. HIPAA Training

Refer to HIPAA IRB Policy 14 for HIPAA training requirements.

IX. GCP

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials must be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).

This applies to all NIH-funded investigators and clinical trial site staff who are responsible for the conduct, oversight, or management of NIH-funded clinical trials.

Definitions:

a. A clinical trial is defined by NIH as a research study in which one or more human subjects 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.
b. The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
c. An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.
d. Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Source: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html

e. Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
f. Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

Acceptable training includes:

1. CITI Good Clinical Practice Course
2. NIH Good Clinical Practice training modules specific to social and behavioral research (https://obssr.od.nih.gov/training/web-based-learning/good-clinical-practice-for-social-and-behavioral-research-elearning-course/)
3. NIAID GCP Course (https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx)
4. National Drug Abuse Treatment Clinical Trials Network GCP course https://gcp.nidatraining.org/
5. Other GCP as approved by the Vice Provost for Research

Training must be completed every 3 years. At the time of initial submission and continuing review of NIH-funded clinical trials, IRB Coordinators will verify the presence of current GCP training for study staff meeting the definitions above. For studies subject to the revised Common Rule , for studies that no longer undergo continuing review, IRB Coordinators will monitor the status of GCP training for study staff administratively.

X. Additional Training

When appropriate, East Tennessee State University will conduct activities (e.g., forums, lectures, pamphlets, public relations, guest speakers, etc.) designed to enhance participants', prospective participants', and the community's understanding of human research. ETSU will evaluate its outreach activities and make content and programmatic changes when appropriate.

In-depth instruction on specific topics is also available, and will be scheduled by IRB staff in response to departmental request.

In addition, basic training materials, including the *Belmont Report,* and links to the pertinent Federal regulations and other resources, are available on the IRB website http://www.etsu.edu/irb. All IRB forms and related information are also posted on the website.

In addition, the Policies and Procedures Manual is also available on-line, as is specific guidance directed to graduate students, residents, etc.

The IRB Staff create a quarterly newsletter containing information about new developments in policies, procedures and regulations as well as a spotlight on a quarterly topic. This newsletter is posted on the IRB webpage, and forwarded to the VA Administrative Officer for VA distribution.

XI. Records

Education records will be monitored and maintained by the OPHRS and (for VA employees) by the VA Research & Development Administration.

XII. IRB Staff Member Training

An IRB New Staff Member checklist will be completed by the Director for each new hire within five months of the staff member's hire date.
Required training consists of:

1. Completion of CITI training within 2 weeks of hire date (VA Biomedical (VA Good Clinical Practice plus CITI Biomedical Research Training), for the medical IRB coordinator, non-VA Social-Behavioral for campus IRB coordinator). A minimum score of 80% is required. IRB staff members not reaching this passing score will be required to review the applicable modules and re-take the tests until a score of ≥80% is obtained.
2. Attendance at both campus and medical IRB meetings
3. Review of policies and federal regulations/guidance/other documents by Director as outlined on ETSU New IRB Member Checklist
4. Preceptorship by Director and/or Coordinator for provision of guidance and support during orientation period

References:

IRB web site: www.etsu.edu/irb
CITI web site: https://about.citiprogram.org/en/homepage/
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html