Effective: October 19, 2015	Revised: March 4, 2016	Revision: 1
Responsibility: OCR		Page 1 of 4
Policy 1.5.1		

HUMAN SUBJECTS PROTECTION AND ETHICS EDUCATION POLICY AND PROCEDURE

1. PURPOSE: The purpose of this policy is to provide the minimum requirements and process for verifying educational training in research ethics and the protection of human research subjects.

2. POLICY: All Investigators and research staff engaged in human subjects research are required to complete education in research ethics and human subjects protection. This requirement reflects the University's commitment to the protection of the rights and welfare of human subjects in research..

3. PROCEDURES:

   A. Investigator and research staff education

      (1) Investigators and research staff engaged in exempt or non-exempt human research must complete the Biomedical Research or Social & Behavioral Research course through the University of Miami's Collaborative Institutional Training Initiative (CITI) Program prior to institutional activation of a research project or approval of the addition of new personnel to an existing protocol. CITI courses are accessible at https://www.citiprogram.org. An overall passing score of 80 % (average of all quizzes) must be obtained in order to obtain credit for a course and download a certificate of completion. CITI training must be renewed every three years by completing the applicable refresher course(s) unless stated otherwise.

      a. The Biomedical Research or the Social and Behavioral Research course (and their refreshers) are deemed acceptable as meeting the minimum required training when engaged in research at South Texas Veterans Health Care System (STVHCS), University Health System (UHS) or the University of Texas Health Science Center at San Antonio (UTHSCSA).

      1. The **Biomedical Research** initial course consists of:
         - Belmont Report and CITI Course Introduction
         - History and Ethics of Human Subjects Research
         - Basic Institutional Review Board (IRB) Regulations and Review Process
         - Informed Consent
         - Records-Based Research
         - Populations in Research Requiring Additional Considerations and/or Protections
         - Social and Behavioral Research (SBR) for Biomedical Researchers
         - Research and HIPAA Privacy Protections
         - Hot Topics
         - Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
         - Conflicts of Interest in Research Involving Human Subjects
         - University of Texas Health Science Center San Antonio Module

      2. The **Social and Behavioral Research (SBR)** initial course consists of:
         - Belmont Report and CITI Course Introduction
         - History and Ethics of Human Subjects Research
         - Defining Research with Human Subjects – SBE
         - Basic Institutional Review Board (IRB) Regulations and Review Process

- Assessing Risk - SBE
- Informed Consent
- Social and Behavioral Research (SBR) for Biomedical Researchers
- Research and HIPAA Privacy Protections
- Hot Topics
- Conflicts of Interest in Research Involving Human Subjects
- University of Texas Health Science Center San Antonio Module

(2) The Practice Based Research course (and its refreshers) is deemed acceptable as meeting the minimum required training for Exempt Research conducted at University Health System (UHS) or the University of Texas Health Science Center at San Antonio (UTHSCSA).

a. The **Practice Based Research** initial course consists of:
   - Basic Institutional Review Board (IRB) Regulations and Review Process
   - Belmont Report and CITI Course Introduction
   - Informed Consent
   - Records-Based Research
   - Research and HIPAA Privacy Protections
   - University of Texas Health Science Center San Antonio Module

(3) Human subjects protection training located on the Institute for Integration of Medicine and Science (IIMS) website: (http://iims.uthscsa.edu/community_pbrn.html) is deemed acceptable as meeting the minimum required training for Practice-Based Research Network (PBRN) members and staff conducting research at University Health System (UHS) or the University of Texas Health Science Center at San Antonio (UTHSCSA). This principal investigator is responsible for ensuring researchers on his/her studies complete initial training and are re-certified every 2 years.

(4) All principal investigators conducting an investigator-initiated study involving a drug or device must complete the CITI module titled “General Researchers (GCP – ICH Focus) and, either “Sponsor Investigators with IDEs (GCP-Devices)”, or “Sponsor-Investigators with INDs (GCP – U.S. FDA Focus”, as applicable.

a. The **General Researchers (GCP – ICH Focus)** initial course consists of:
   - The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics
   - Overview of New Drug Development
   - Overview of ICH GCP
   - ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations
   - Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
   - Investigator Obligations in FDA-Regulated Research
   - Managing Investigational Agents According to GCP Requirements
   - Informed Consent in Clinical Trials of Drugs and Biologics
   - Monitoring Clinical Trials of Drugs by Industry Sponsors
   - Audits and Inspections of Clinical Trials of Drugs and Biologics
   - Detecting and Evaluating Adverse Events Reporting Serious Adverse Events in Investigations of Drugs and Biologics
   - Completing the CITI GCP Course

b. The **Sponsor Investigators with IDEs (GCP-Devices)** initial course consists of:
   - Humanitarian Use Devices (HUDs)
   - The CITI Good Clinical Practice Course for Clinical Trials Involving Investigational Medical Devices
   - Conducting Investigator-Initiated Clinical Trials of Medical Devices
   - Investigator Obligations in Clinical Trials of Medical Devices
   - Managing Investigational Devices According to GCP Requirements
   - Overview of U.S. FDA Regulations for Medical Devices
   - Informed Consent in Clinical Trials of Devices
   - Monitoring Clinical Trials of Devices
   - Audits and Inspections of Clinical Trials of Devices
   - Reporting Requirements for Device Studies
   - Completing the CITI GCP Course

c. The **Sponsor-Investigators with INDs (GCP – U.S. FDA Focus)** initial course consists of:
   - The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices
   - Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
   - Overview of New Drug Development
   - Overview of ICH GCP
   - ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations
   - Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
   - Investigator Obligations in FDA-Regulated Research
   - Managing Investigational Agents According to GCP Requirements
   - Overview of U.S. FDA Regulations for Medical Devices
   - Detecting and Evaluating Adverse Events
   - Reporting Serious Adverse Events
   - Audits and Inspections of Clinical Trials
   - Monitoring of Clinical Trials by Industry Sponsors
   - Completing the CITI GCP Course

(5) All principal investigators and research staff conducting a NIH funded clinical trial must complete Good Clinical Practice training.

(6) Depending upon the type of research and role being conducted, researchers may also be required to take additional modules through CITI.

a. Supplemental modules include, but are not limited to:
   - Genetic Research in Human Populations
   - Research with Persons who are Socially or Economically Disadvantaged
   - Research with Decisionally Impaired Subjects
   - Illegal Activities or Undocumented Status in Human Research
   - Research with Subjects with Physical Disabilities & Impairments
   - Research Involving Subjects at the End of Life
   - Research with Older Adults
   - Gender and Sexuality Diversity (GSD) in Human Research
   - Research with Critically Ill Subjects
   - Vulnerable Subjects - Research Involving Prisoners
   - Vulnerable Subjects - Research Involving Children
   - Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates

- International Studies
- FDA-Regulated Research
- Vulnerable Subjects - Research Involving Workers/Employees
- I Have Agreed to be an IRB Community Member. Now What?
- Avoiding Group Harms - U.S. Research Perspectives
- Humanitarian Use Devices (HUDs)
- Avoiding Group Harms - International Research Perspectives
- Cultural Competence in Research
- External IRB Review
- Phase I Research: Understanding Phase I Research
- Phase I Research: Protecting Phase I Subjects
- Consent and Subject Recruitment Challenges: Remuneration
- Stem Cell Research Oversight (Part I)
- Stem Cell Research Oversight (Part II)

b. The Office of Clinical Research (OCR) staff review applications for appropriate training of investigators and research staff engaged in research by reviewing Step 2 Institutional Form, Form B-2, or Form Inst M during initial review and during review of amendment/modification requests as appropriate. The staff is able to confirm CITI training by accessing the administrator menu of the website, or by confirming documentation issued by University of Miami's Collaborative Institutional Training Initiative (CITI) Program.

B. Alternative Training Options

(1) Access to Association of Clinical Research Professionals (ACRP) training (located at http://learning.acrpnet.org/partner/uthscsa) is also available to researchers employed by or affiliated with UTHSCSA. Completion of identified ACRP courses indicated on the OCR website may be deemed acceptable as meeting the minimum required training when engaged in human subjects research at the University of Texas Health Science Center at San Antonio (UTHSCSA).

(2) The OCR Director or his/her designee 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.) Documentation must be obtained, maintained and submitted by the trained individual as necessary to indicate that training was completed.

(3) Documentation should be submitted to the OCR by the trained individual as necessary to indicate that training was completed (or refresher training was completed at least once every three years).

4. REFERENCES:

21 CFR 50 – Protection of Human Research Subjects (Protection of Human Subjects)
45 CFR 46 – Protection of Human Subjects (Common Rule)
21 CFR 56 (IRBs)
21 CFR 312 (IND)
21 CFR 812 (IDE)