HUMAN RESEARCH PROTECTION PROGRAM POLICY AND PROCEDURE

5.2 RESEARCH EDUCATION AND TRAINING

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD) **EFFECTIVE DATE: June 7, 2021**

I. POLICY STATEMENT

A. The University of Texas Southwestern Medical Center recognizes the importance of promoting the highest ethical standards in the conduct of research. As such, University of Texas Southwestern Medical Center has a comprehensive educational program that ensures that individuals involved in the conduct or oversight of exempt and/or non-exempt human subjects' research understand the ethical principles and regulatory requirements related to the protection of human subjects. With the exception of the Institutional Official, this education must be refreshed every three years to ensure the most up-to-date knowledge. HIPAA in Research training is completed one time.

B. All investigators and research staff engaged in exempt and non-exempt human research under the UT Southwestern FWA must complete appropriate education in research ethics, human research protections and regulatory policy prior to final IRB approval to conduct the research.

C. All IRB members and chairs must complete appropriate education in research ethics, human research protections, IRB responsibilities and regulatory policy within three months of appointment to the board or appointment as IRB Chair or Vice Chair.

D. All Human Research Protection Program Department (HRPPD) staff must complete appropriate education in human research protections and regulatory policy within three months of employment in the HRPPD.

E. The Institutional Official (IO) must complete appropriate education in human research protections and institutional responsibilities under the federalwide assurance within three months of designation as the IO.

II. SCOPE

A. This policy and procedure applies to the following:

1. UT Southwestern Medical Center investigators and Research staff
2. IRB Members and IRB Chairs
3. Human Research Protection Program Department (HRPPD) staff
4. Institutional Official

III. PROCEDURE FOR POLICY IMPLEMENTATION

A. INVESTIGATOR AND RESEARCH STAFF EDUCATION

1. Training is hosted on the Collaborative Institutional Training Initiative (CITI) website.

2. Investigators and research staff engaged in research must complete the Human Subjects Protection Course and the HIPAA in Research Course. The following modules are required for each course:

    a. Human Subjects Research (HSR)

        i. Belmont Report and CITI Course Introduction
        ii. History and Ethics of Human Subjects Research
        iii. Basic Institutional Review Board (IRB) Regulations and Review Process
        iv. Informed Consent
        v. Social and Behavioral Research (SBR) for Biomedical Researchers
        vi. Records-Based Research
        vii. Genetic Research in Human Populations
        viii. Populations in Research Requiring Additional Considerations and/or Protections
        ix. Vulnerable Subjects - Research Involving Children
        x. Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates
        xi. FDA-Regulated Research
        xii. Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
        xiii. Defining Research with Human Subjects
        xiv. Assessing Risk
        xv. Privacy and Confidentiality

    b. HIPAA in Research

        i. Facing The Privacy Rule Challenges for Clinical Researchers
        ii. Why The Privacy Rule Is Important to Clinical Researchers
        iii. How Do Researchers Obtain, Create, Use and/or Disclose PHI?
        iv. UT Research Authorizations
        v. IRB Waiver of Authorizations
        vi. De-identification of PHI
        vii. Limited Data Set
        viii. Data Use Agreements and Limited Data Sets
        ix. Recruitment for Participation in Research Studies
        x. Use of PHI for Research on Decedents
        xi. Transition Provisions
        xii. Research Accounting Statements

3. Investigators and research staff conducting: a) research involving a drug or device or b) Clinical Trials supported by the National Institute of Health (NIH) must complete the GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) course

    a. The following modules are required for this course:

        i. The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices
        ii. Overview of New Drug Development

iii. Overview of ICH GCP
iv. ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
v. Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
vi. Investigator Obligations in FDA-Regulated Research
vii. Managing Investigational Agents According to GCP Requirements
viii. Overview of U.S. FDA Regulations for Medical Devices
ix. Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
x. Detecting and Evaluating Adverse Events
xi. Reporting Serious Adverse Events
xii. Monitoring of Clinical Trials by Industry Sponsors
xiii. Audits and Inspections of Clinical Trials
xiv. Completing the CITI GCP Course
xv. Humanitarian Use Devices (HUDs)
xvi. Phase I Research: Understanding Phase I Research
xvii. Phase I Research: Protecting Phase I Subjects

4. Renewal of UTSW CITI training is accomplished by completing the applicable refresher courses

5. The Human Research Protections Program (HRPPD) staff screen applications for appropriate training of investigators and research staff engaged in research during initial/ continuation review and during review of amendment/modification requests as appropriate. The staff is able to confirm CITI training by accessing the administrative page of the CITI website.

B. IRB Members and Chairs

1. IRB members and chairs complete the IRB Member CITI training.

a. The UTSW IRB Member Course is designed to provide the members with information about all types of research. This course includes HSR, GCP, and HIPAA in Research courses as well as the following modules to enhance the IRB Member knowledge of the federal regulations:

i. Vulnerable Subjects - Research Involving Prisoners
ii. Avoiding Group Harms - U.S. Research Perspectives
iii. Avoiding Group Harms - International Research Perspectives
iv. Research and HIPAA Privacy Protections
v. International Research - SBE
vi. Internet-Based Research - SBE
vii. Cultural Competence in Research
viii. International Studies
ix. Are You Thinking About Being in a Research Study?
x. I Have Agreed to be an IRB Community Member. Now What?
xi. The IRB Member Module - "What Every New IRB Member Needs to Know"
xii. Vulnerable Subjects - Research Involving Workers/Employees

b. IRB Chairs will complete the following modules:

i. Role and Responsibilities of an IRB Chair
ii. IRB Chair Meeting Responsibilities
iii. The IRB Chair's Role Outside of the IRB Meeting

c. The HRPPD staff use the HRPPD database to monitor IRB member training and provide regular reports to the members, chair and IRB Director of training status and impending expiration dates.

2. Orientation of new IRB Members - following appointment as a member on the IRB and prior to serving as reviewers (primary or secondary), IRB members, ex-officio members, and alternate members receive the following training:

   a. The HRPPD staff provides new members with a general orientation. Following the annual assignment of members, the HRPPD provides an orientation session for all new and current board members.

   b. A new member unable to attend the general orientation session or added to the board later in the year, may meet with the HRPP Director, Chair or designee to review roles and responsibilities

3. IRB members are provided with continuing education as part of each meeting's standard agenda. The education topic is generally selected to coincide with an issue from one of the studies scheduled for review at the meeting.

   a. Additional educational materials containing ethical and regulatory guidance for the review of protocols involving a specialized area, (i.e., gene therapy or tissue banking) or selected vulnerable subject populations (i.e., prisoners) are provided specifically to primary reviewer or to all members as appropriate.

4. The HRPPD provides funding for the Chairs to attend national continuing education conferences, as budgets permits

C. The Human Research Protection Program Department (HRPPD) staff

1. The HRPPD staff must complete the UTSW IRB Member education (as described above).

2. The HRPPD staff must complete individualized on-the-job training and orientation as determined by their job description. New staff must review all existing HRPPD/IRB policies and procedures.

3. The HRPPD staff is provided with continuing education during regularly scheduled staff meetings (generally weekly). The education topic is generally selected to coincide with an issue from one of the studies scheduled for review at the meeting or related to a recent issue or problem.

4. The HRPPD subscribes to IRB related educational materials (i.e., IRB Forum listserv, Quorum listserv, the Human Research Report) which is circulated to the staff.

5. The HRPPD provides funding for the staff to attend national continuing education conferences, webinars, etc. as budgets permit.

6. The Assistant Vice President for Human Research Administration (AVPHRA), the IRB Director or designee tracks training status of the staff.

D. The Institutional Official (IO)
   1. *Required* All three training models provided in the Office for Human Research Protection's (OHRP) "Human Subject Assurance Training"
      a. HHS Regulations & Institutional Responsibilities
      b. Investigator Responsibilities & Informed Consent
      c. Human Research Protections Program
   2. *Optional* Institutional Official Training hosted on the Collaborative Institutional Training Initiative (CITI) website. Modules include:
      a. Introduction to Being an Institutional Official (IO)
      b. IO Knowledge Requirements: Human Subject Protections
      c. Expectations of the IO
      d. Challenges of Being an IO: Human Subject Protections

E. Optional Educational Offerings for research community
   1. UT Southwestern regularly offers courses to provide supplemental education for research teams. Courses available include (but are not limited to):
      a. IRB Orientation
      b. Research Coordinator 101
      c. Research Coordinator 201
      d. Topics in Informed Consent
      e. ClinCard Training
      f. Budget Estimation and Negotiation
      g. Clinical Research Coordinator Forum
      h. Hot Topics (as needed)
   2. Other educational offerings as available and applicable include (but are not limited to):
      a. Research Matters
         i. These educational sessions are designed to allow the research community the opportunity to provide direct feedback to the HRPPD staff, allow for a question-and-answer period, and a formal presentation on topics related to human research protection.
         ii. The HRPPD schedules these sessions on a regular basis and as needed.

b. Webinars

i. As applicable webinar topics are available, the HRPPD may fund access to webinars for appropriate audiences (research offices, IRB members, HRPPD staff, researchers, etc.).

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS
NIH GCP Policy - POLICY ON GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS; NOT-OD-16-148

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
January 2019	HRPP	Revision to reference 2019 common rule
June 2017	HRPP	Added GCP renewal requirements per NIH
January 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures