1 PURPOSE

1.1 This SOP establishes the procedure for educating Texas A&M University (TAMU) Institutional Review Board (IRB) members, IRB staff, investigators, and site research staff to ensure adequate training in human research protection and qualifications of all staff.

1.2 The SOP begins when the individual becomes an IRB member or is engaged in TAMU human subjects research.

1.3 The guidance ends when the individual's involvement with TAMU human subjects research ceases.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 SOP Statement

3.1 The TAMU HRPP offers comprehensive human research protection education to the TAMU research community and affiliate organizations.

3.2 Education is offered in many areas of research, including ethical standards, TAMU rules and procedures, and applicable federal, state, and local law. The foundation of ethical training at TAMU is the Belmont Report, which is made available through the HRPP website and the Collaborative Institutional Training Initiative (CITI) website.

3.3 IRB members, IRB staff, investigators, and all site research staff involved in the design, conduct, or reporting of research are required to complete initial education and training on human subject protection and refresher courses, as applicable.

3.3.1 Investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory and policy requirements, and should provide evidence as needed of such qualifications through any licensure, certifications, up-to-date curriculum vitae or other appropriate means of verification, evidence of CITI training and/or other relevant courses requested by sponsor or funding agency, the IRB, and/or the regulatory authorities.

3.3.2 IRB approval will not be granted for proposed research in which members of the research team have not completed the required human research protections training.

3.3.3 Initial training and education requirements and refresher updates including timeframes is specified for IRB members, IRB staff, and site research staff.

3.4 All educational requirements by all site research staff must be met for IRB study approval (initial and continuation).

3.4.1 If site research staff education requirements are not fulfilled, the study is not approved until all site research staff meets requirements.

3.5 Monitoring of education requirements of IRB members and IRB staff is performed regularly as applicable to the role and all site research staff is monitored as described in section 4.4.

3.6 External research staff engaged in research under the purview of a TAMU IRB are required to complete the educational requirements in Group 4 Required Training. External research staff are non-Texas A&M personnel with limited study roles and assigned duties in remote areas, foreign countries or other exceptional circumstances as determined by the IRB.

3.6.1 Note: Any external investigator that completed the NIH training as alternative education prior to NIH removing this educational course can use the NIH training to support the educational requirements until the NIH training certification expires.

3.6.2 Investigators should consult with the IRB staff prior to assigning Group 4 Requirements to external research staff.

4 RESPONSIBILITIES

4.1 IRB and HRPP staff performs these procedures.

4.2 IRB members, IRB/HRPP staff, and all site research staff must fulfill the required training and information requirements set forth in this guidance.

4.3 Investigators ensure that site research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

4.4 IRB staff monitors research staff education requirements during the initial IRB review process and during the continuing review process or annual administrative update.

4.4.1 Investigator training status is automatically captured in the iRIS system to facilitate appropriate monitoring and oversight.

4.4.2 iRIS displays the following investigator training status:

4.4.2.1 No training

4.4.2.2 Training expired

4.4.2.3 Training complete

4.4.3 Should investigator training expire between the monitoring periods as described in 4.4 the expiration will not be considered non-compliance; this grace period shall not extend beyond any required continuing review or similarly required annual administrative update.

4.5 The CITI online training program automatically sends reminder notices to each registered investigator of pending training expiration at 90, 60 and 30 days prior to expiration of training courses.

5 PROCEDURE

5.1 Education Planning

5.1.1 The HRPP reviews and updates this HRPP education guidance annually or as needed.

5.1.2 The HRPP incorporates input received from IRB members, IRB/HRPP staff, and investigators and from monitoring and evaluation activities. Trends in research at TAMU are considered and new federal, state, or local regulations (or published guidance's) are integrated. Compliance activities (e.g., internal and external reviews or audits) also provide input into the education plan.

5.1.3 A list of educational activities offered to the TAMU research community is maintained by the HRPP.

5.2 Required Initial and Continuing Training:

5.2.1 **Investigator and Site Research Staff Group 1 Required Training:**

Investigator and Research Staff involved in Clinical Studies (drugs, devices, biologics, invasive procedures) Required Training		
	Course	Timeline
Initial Training	CITI Biomedical Research Basic	Prior to IRB submission of research
	*CITI Good Clinical Practice	Prior to IRB submission of research
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Prior to IRB submission of research

	***TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Prior to IRB submission of research
Refresher Courses	CITI Biomedical Research Refresher	Every 5 years
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required
	***TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Every 4 years or upon change

*When using FDA regulated test articles or as required by sponsor or funding agency.
** When accessing, recording or disclosing PHI for research purposes.
*** When involved in funded research in accordance with University Rule 15.01.03.MI.

5.2.2 **Investigator and Site Research Staff Group 2 Required Training:**

Investigator and Research Staff involved in Social & Behavioral Studies Group 2 (Surveys, Qualitative, Educational, Record Reviews) Required Training		
	Course	Timeline
Initial Training	CITI Social and Behavioral Research Basic	Prior to IRB submission of research
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Prior to IRB submission of research
	***TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Prior to IRB submission of research
Refresher Courses	CITI Social and Behavioral Research Refresher	Every 5 years
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required
	***TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Every 4 years or upon change

*When using FDA regulated test articles or as required by sponsor or funding agency.
** When accessing, recording or disclosing PHI for research purposes.
*** When involved in funded research in accordance with University Rule 15.01.03.MI.

5.2.3 **IRB Members Group 3 Required Training:**

IRB Member Required Training		
	Course	Timeline
Initial Training	CITI IRB Members Basic	Within 60 days of appointment
	TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Within 60 days of appointment
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Within 60 days of appointment
	IRB Member Orientation	Prior to voting and review assignments;

Refresher Courses	CITI IRB Members Refresher	Every 5 years
	TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Every 4 years or upon change
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required

HRPP/IRB Group 1,2 & 3 Staff Required Training:

HRPP/IRB Staff Required Training		
	Course	Timeline
Initial Training	CITI IRB Members Basic	Within 30 days of employment
	TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Within 30 days of employment
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Within 30 days of employment
Refresher Courses	CITI IRB Members Refresher	Every 5 years
	TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Every 4 years or upon change
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required

HRPP/IRB Group 4 Required Education for External or Foreign Research Staff:

HRPP/IRB Staff Required Training		
	Course	Timeline
Initial Training	CITI Group 4 Educational Requirements: History and Ethical Principles (SBE: 490) Informed Consent (SBE: 504) Privacy and Confidentially (SBE:505)	Prior to Approval of Research
Refresher Courses	CITI Group 4 Educational Requirements:	Every 5 years

5.2.4 **Institutional Official Required Training:**

Institutional Official Required Training		
	Course	Timeline
Initial Training	CITI Institutional/Signatory Official: Human Subject Research	Within 60 days of appointment

Initial and Ongoing	TRAINTRAQ Financial Conflicts of Interest in Research - 2111716	Annually or upon change
Initial and Ongoing	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required

5.2.5 New TAMU employees may use previously completed CITI human subjects' protections training from their prior institution if within the applicable timeframe.

5.2.6 There may be additional protocol-specific educational requirements or certifications required for investigators and site research staff based on additional regulations (e.g., Department of Defense [DoD] or sponsor requirements, due to the complexity and risk of the research).

5.3 Training and Education Records:

5.3.1 All IRB-required education records and appropriate certificates of completion are maintained by the investigator. Individual investigators maintain their own training records and provide to the IRB as required.

5.3.2 IRB staff will be given access to the applicable education sites to confirm completion of requirements for all individuals covered by this SOP.

5.4 Ongoing Education - Contributing to the Improvement of Expertise

5.4.1 HRPP-sponsored education opportunities for continuing education in human research protections are provided on a periodic basis and upon request.

5.4.2 IRB member, IRB staff, investigators, and all site research staff attendance is encouraged at regulatory and professional meetings and conferences both locally at TAMU and nationally.

5.4.3 HRPP supports and encourages professional certification for qualified HRPP/IRB staff and investigators.

5.4.4 Ongoing education will be provided to IRB members at convened meetings.

6 MATERIALS

6.1 Collaborative Institutional Training Initiative Program (CITI)

6.2 TAMU TRAINTRAQ

7 REFERENCES

7.1 AAHRPP I.1.E