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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 or staff 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 Revised from the 5/1/2022 version
- 2.2 Revised from the 6.11.2020 version
- 2.3 Revised from 10/3/2019 version
- 2.4 Revised from 8/15/2019 version
- 2.5 Revised from 1/9/2019 version
- 2.6 Revised from 11/15/2018 version
- 2.7 Revised from 5/30/2017 version

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 available through the OHRP website: [The Belmont Report | HHS.gov](https://www.hhs.gov/ohrp/belmont-report/).
- 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 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 Initial training and education requirements and refresher updates including timeframes is specified for IRB members, IRB staff, and site research staff, below.
- 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, IRB staff, and all site research staff is performed regularly as applicable to the role.
- 3.6 Human subjects protection educational courses completed at other institutions may be accepted when appropriate if the courses are current and equivalent to the TAMU HRPP requirements.

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- 3.7 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. Examples include external researchers with limited roles, in remote areas, foreign countries or other exceptional circumstances as determined by the IRB.
- 3.7.1 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 perform 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 continuation request process.

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:

Group 1 Required Training: Investigators and Research Staff involved in Clinical Studies (drugs, devices, biologics, invasive procedures)****		
	Course	Timeline
Initial Training	CITI Biomedical Research Basic	Prior to IRB submission of research
	*Good Clinical Practice	Prior to IRB submission of research
	**TRAINTRAQ Course #2114226: HIPAA Training for Texas A&M Faculty, Staff & Students or equivalent; External researchers may use CITI - Information Privacy and Security	Prior to IRB submission of research
	*** TRAINTRAQ Course #2111716: Financial Conflicts of Interest in Research; External researchers may use CITI Conflicts of Interest	As required by system regulation 15.01.03
Refresher Courses	CITI Biomedical Research Refresher	Every 5 years
	*Good Clinical Practice	Every 3 years

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	**TRAINTRAQ Course #2114226: HIPAA Training for Texas A&M Faculty, Staff & Students or equivalent; External researchers may use CITI - Information Privacy and Security	Every 5 years or as required by institutional policy
	*** TRAINTRAQ Course #2111716: Financial Conflicts of Interest in Research; External researchers may use CITI Conflicts of Interest	As required by system regulation 15.01.03

*As required by sponsor or funding agency.

** When accessing, recording or disclosing PHI for research purposes.

*** When required for externally funded research in accordance with SAP 15.01.03.

**** Group 1 or 3 may substitute for Group 2 when appropriate.


Group 2 Required Training: Investigators and Research Staff involved in Social & Behavioral Studies (Surveys, Qualitative, Educational, Record Reviews)****		
	Course	Timeline
Initial Training	CITI Social and Behavioral Research Basic	Prior to IRB submission of research
	*Good Clinical Practice	Prior to IRB submission of research
	**TRAINTRAQ Course #2114226: HIPAA Training for Texas A&M Faculty, Staff & Students or equivalent; External researchers may use CITI - Information Privacy and Security	Prior to IRB submission of research
	*** TRAINTRAQ Course #2111716: Financial Conflicts of Interest in Research; External researchers may use CITI Conflicts of Interest	As required by System Regulation 15.01.03
Refresher Courses	CITI Social and Behavioral Research Refresher	Every 5 years
	*Good Clinical Practice	Every 3 years
	**TRAINTRAQ Course #2114226: HIPAA Training for Texas A&M Faculty, Staff & Students or equivalent; External researchers may use CITI - Information Privacy and Security	Every 5 years or as required by institutional policy
	*** TRAINTRAQ Course #2111716: Financial Conflicts of Interest in Research; External researchers may use CITI Conflicts of Interest	As required by system regulation 15.01.03

*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.

**** Group 2 or 3 may substitute for Group 1 when appropriate.

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Group 3: IRB Member Required Training*		
	Course	Timeline
Initial Training	CITI IRB Members Basic or equivalent**	Within 90 days of appointment
	IRB New Member Orientation	Prior to review assignments

** Upon expiration of previous requirements for existing IRB members

Group 3: HRPP/IRB Staff Group Required Training:		
	Course	Timeline
Initial Training	CITI Biomedical Research Basic or CITI Social & Behavioral Research Basic; CITI Good Clinical Practice & CITI IRB Members Basic	Within 30 days of employment
	TRAINTRAQ Course #2114226: HIPAA Training for Texas A&M Faculty, Staff & Students or equivalent;	Within 30 days of employment
	TRAINTRAQ Course #2111716: Financial Conflicts of Interest in Research;	Within 30 days of employment
Refresher Courses	CITI IRB Members Refresher	Every 5 years

Group 4 Required Education for External Researchers with Limited Roles		
	Course	Timeline
Initial Training	CITI Group 4 Educational Requirements: History and Ethical Principles (SBE: 490) Informed Consent (SBE: 504) Privacy and Confidentiality (SBE:505)	Prior to Approval of Research
Refresher Courses	CITI Group 4 Educational Requirements:	Every 5 years

Institutional Official Required Training		
	Course	Timeline
Initial Training	CITI Institutional/Signatory Official: Human Subject Research	Within 90 days of appointment

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- 5.2.1 New TAMU employees may use previously completed CITI human subjects' protections training from their prior institution if within the applicable timeframe.
- 5.2.2 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 as needed.

6 MATERIALS

- 6.1 Collaborative Institutional Training Initiative Program (CITI)
- 6.2 TAMU TRAINTRAQ

7 REFERENCES

- 7.1 AAHRPP I.1.E