Policy Name: Research Training Requirements	
Policy Owner: Research Activities and Compliance Committee	**Effective Date:** 01/30/2024
Approved By: System Performance Alignment & Innovation (SPAN)	**Last Reviewed Date:** 01/30/2024

1.0 Scope:

1.1 Applicable Entities:
This policy applies to:

- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals
- Texas Health Physicians Group
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities (except those listed in the Formulation and Adoption of System-Wide Policies and Procedures in Section 4.1.6 or in Section 4.1.7)

1.2 Applicable Departments:
This policy applies to all departments.

1.3 Applicable Personnel:
Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record.

2.0 Purpose:

2.1 To establish and communicate the training requirements for the Texas Health Human Research Protection Program (HRPP) office staff, research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record.

3.0 Policy Statement(s):

3.1 HRPP office staff, research investigators and research study staff engaged in research activities subject to Texas Health institutional oversight and the oversight of an applicable Texas Health IRB of Record must complete initial and periodic refresher training as specified in this policy. The training curriculum and materials are dependent on the individual's role and responsibilities related to research activities.

For purposes of this policy, the primary roles include:

- HRPP Office Staff
- Research Investigators and Research Study Staff

4.0 Policy Guidance:

4.1 Texas Health institutional approval and IRB approval will not be granted until all required training is complete. All members of the research community are required to maintain and keep current training credentials on file with the Texas Health Human Research Protection Program (HRPP) within the electronic Institutional Review Board (eIRB) system used by Texas Health. Required training must be renewed as specified in this policy.

4.2 Failure to complete required training could result in the interruption of the research investigator's research activities.

4.3 Any person who obtained HSP certification deemed equivalent by the HRPP Office will be allowed to maintain that certification until its expiration, which has been defined as three years from the date training was completed. Upon expiration, he/she will be required to take the appropriate, designated HSP course Texas Health utilizes at the time of re-certification.

5.0 Definitions:

5.1 eIRB - The electronic information system(s) that are used by HRPP office staff and by research investigators and research study staff to submit initial and continuing review applications and other information necessary for the Texas Health IRB of Record to carry out review and oversight responsibilities.

5.2 Health Insurance Portability and Accountability Act (HIPAA) - Federal privacy and information security laws and regulations generally designed to protect personal health information with specific provisions applicable to patient privacy requirements for research activities.

5.3 Human Subject Protection Training - This training consists of online modules that educate the user on how to protect human subjects when conducting research. Topics covered include regulatory framework, HIPAA, informed consent, vulnerable populations, IRBs, conducting clinical research, and conflicts of interest.

5.4 Institutional Review Board (IRB) - The Committee or Committee(s) authorized to serve as the IRB(s) of Record for Texas Health and to review and monitor research involving human subjects in accordance with ethical standards, laws and regulations.

5.5 Research Community - Research investigators, research staff, HRPP office staff and any other persons involved in research activities subject to Texas Health institutional oversight and oversight by the Texas Health IRB of Record.

6.0 **Responsible Parties**:

This policy covers any Texas Health employee or agent in which Texas Health is engaged and conducts research within any Texas Health facility or with Texas Health equipment or resources.

6.1 Research Investigators and Research Study Staff

6.1.1 *Human Subject Protection (HSP):* Research investigators and research staff must complete HSP training as specified by the IRB prior to initial IRB approval of research. There are no exceptions to this training requirement. Refresher training is required every three years.

6.1.2 *HIPAA Privacy Training:* Research investigators and research study staff must review this training once prior to protocol submission. Refresher training will be required as appropriate with regulatory changes.

6.1.3 *Good Clinical Practice (GCP) Training:* Research investigators and research study staff who are involved in the conduct of industry-sponsored or NIH-sponsored, multi-center clinical research studies will be required to complete GCP training prior to the initiation of research activities. When taken, GCP refresher training is required at a minimum of every three years.

6.1.4 *Texas Health Research Policy Review:* Specific Texas Health policies, which can be found on the Texas Health HRPP Website, must be reviewed prior to the institutional and IRB approvals of research. Information of interest include:

a. Federal Regulations Regarding Research
b. Corporate Policies
c. Other policies as deemed necessary.

6.1.5 *Current License(s)*: Copies of current licenses are required for all licensed professionals who are not credentialed at a Texas Health facility. All such professionals should keep licenses current in accordance with requirements of the licensing agency.

6.2 HRPP Office Staff

6.2.1 HRPP Office Staff will be trained to Texas Health research policies, including internal HRPP office procedure(s). In addition, supplemental training related to staff/job functions will be provided as needed.

6.2.2 HRPP Office staff will complete required Human Subject Protection (HSP) and HIPAA Privacy training. Refresher of HSP training will be required every three years. Refresher HIPAA Privacy training will be required as appropriate with regulatory changes.

6.2.3 HRPP Office Staff are expected to remain current with industry standards related to the discussion of ethical, regulatory, and policy concerns with human subjects research. HRPP Office Staff are encouraged to attend local, regional, and national conferences or workshops regarding the protection of human research subjects and other related educational activities.

6.3 Texas Health Research Activities and Compliance Committee (RACC) has responsibility for the oversight and implementation of this policy.

7.0 External References:

7.1 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

7.2 45 CFR 46

7.3 45 CFR 160, 162 & 164, Privacy Rule (HIPAA)

8.0 Related Documentation and/or Attachments:

8.1 Human Research Protection - THR System Policy

8.2 Research Compliance Program - THR System Policy

8.3 *Training Updates:* In the event that regulatory/policy standards change, the THR HRPP website will be updated, and a notification will be sent to report these new changes, as warranted. In addition, the research training curriculum will be updated accordingly.

8.4 *Conferences and Workshops:* The Research Community is encouraged to participate in local, regional, or national conferences and workshops, including those sponsored by the following organizations:

a. Association for the Accreditation of Human Research Protection Programs (AAHRPP)
b. Office for Human Research Protections (OHRP)
c. Public Responsibility in Medicine and Research (PRIM&R)

8.5 *HRPP website:* Educational topics are available on the THR HRPP website along with guidance, resource documents, application forms, and links to regulatory agencies and other helpful resources.

8.6 Research Record Retention - THR System Policy

9.0 Required Statements:

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.