

Policy Name: Research Engagement	
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
Page 1 of 2	

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 define when Texas Health is engaged in a research activity.

3.0 Policy Statements:

3.1 Texas Health is defined as engaged in the research study when:

3.1.1 An Entity of Texas Health has contracted with a sponsor to conduct a clinical trial; or

3.1.2 Texas Health's employees or agents (medical staff member or similarly affiliated with a Texas Health entity) provide support, research coordination or hospital services to investigators in the conduct of a clinical trial; or

3.1.3 An investigator recruits for the research study using Texas Health premises (i.e., fliers, handouts, etc.) or communication resources (i.e., email, electronic signs, etc.) including study subject recruitment or other study solicitation activities; or

Policy Name: Research Engagement
Page 2 of 2

3.1.4 The subject is consented to participate in the study while a patient at a Texas Health entity.

3.2 Texas Health would not be considered engaged for solely providing a standard of care service(s) to a patient consented outside of their hospital stay.

4.0 Policy Guidance:

4.1 The Principal Investigator is responsible for know whether his/her study engages THR and as such follows the requirements.

5.0 Definitions:

Not Applicable

6.0 Responsible Parties:

6.1 Texas Health Research Activities and Compliance Committee (RACC)

6.1.1 Has responsibility for the oversight and implementation of this policy.

7.0 External References:

Not Applicable

8.0 Related Documentation and/or Attachments:

8.1 Research Advertisement and Recruitment - THR System Policy

8.2 Human Research Protection Program (HRPP) - 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.