

Policy Name: Research Contracts	
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
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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 This policy describes the requirements for contractual obligations when Texas Health is defined as engaged in a research project.
- 2.2 This policy describes the requirements for contractual obligations when Texas Health is not engaged, but a service is requested in relation to a research project.

3.0 Policy Statements:

- 3.1 A contract must be in place with Texas Health for all sponsored clinical trials related to human research conducted at any THR Entity or in which Texas Health is engaged.
- 3.2 The contract may be written between the Texas Health entity and the sponsor or between the Texas Health entity, the Sponsor, and the Principal Investigator, if the Principal Investigator is not an employee of Texas Health. Texas Health employees that are serving as a Principal Investigator may sign as read and acknowledged on the research agreement but may not be a contracted party to the agreement.

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- 3.3 Texas Health site approval will not be released for the study to be initiated until a signed contract has been fully executed.
- 3.4 The Texas Health research entity, Texas Health Research & Education Institute (THRE), if not a party to the contract, must sign as read and acknowledge on all contracts.
- 3.5 THRE will be the payee for all revenue from the research study sponsor for those studies in which THRE is engaged in the study or in which the hospital related research revenue is 50% or greater of the total budget of the study.
- 3.6 If the THRE is the payee, THRE will disseminate revenue to the Principal Investigator as per the conditions detailed in a contract between the THRE and the Principal Investigator.
- 3.7 For studies in which the Principal Investigator is the payee of the revenue from the Sponsor, the Principal Investigator will sign a Hospital Service Agreement to indicate what research related revenue will be paid to the THRE on behalf of the Texas Health Entity by the Investigator.
- 3.8 All industry sponsored clinical trials will be assessed a charge for indirect costs incurred by THRE at a rate of 32% which will be payable to THRE.
- 3.9 All grant funded studies will be assessed the allowable federal F&A rate payable to THRE.
- 3.10 If Texas Health is not engaged in the research project, a Purchased Service Agreement is required between the Texas Health entity and the payee of the services. All agreements and payments for services provided will be processed through THRE.
- 3.11 If the event services have been provided and Texas Health has not received study payment from Principal Investigator or Study Sponsor within 6 months from time of study subject receiving hospital treatment, the study will be placed on hold to new enrollment and the Texas Health Research Activities and Compliance Committee (RACC) and the Entity President will be notified.

4.0 Policy Guidance:

- 4.1 The Principal Investigator is responsible for ensuring all contracts and/or agreements have been submitted for review and executed prior to moving forward with a study.

5.0 Definitions:**5.1** Texas Health is defined as engaged in the research study when:

- 5.1.1 An Entity of Texas Health has contracted with a sponsor to conduct a clinical trial; or
- 5.1.2 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
- 5.1.3 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
- 5.1.4 The subject is consented to participate in the study while a patient at a Texas Health entity.
- 5.1.5 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.

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 References

- 8.1 Research Engagement - THR System Policy
- 8.2 Human Research Protection Program (HRPP) - THR System Policy
- 8.3 Hospital Research Services - 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.

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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.