Policy Name: Hospital Research Services	
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 To describes the requirements for the utilization of Texas Health hospital services for a research project.

3.0 Policy Statements:

3.1 All Investigators must submit a Special Admission Form (SAF) to Research Administration within 24 hours of the provision of the service to THREResearchAdministration@texashealth.org (*See Appendix 1*). At a minimum, Patient Name, Medical Record Number and service(s) provided shall be listed on the SAF.

3.2 A copy of the signed research Informed Consent Form (ICF) must be placed in the patient's Medical Record if the patient is participating in a Texas Health engaged research project and the Texas Health service is associated with the research project.

3.3 All standard and non-standard of care services provided by a Texas Health entity for a research project must be reviewed by Research Administration and the appropriate agreement be put into place prior to any services being provided.

3.4 Services determined to constitute a Commercial Service must have a Purchase Service Agreement in place prior to the commencement of the delivery of the service(s). Research Administration shall facilitate all Purchase Service Agreements on behalf of the Texas Health hospital.

3.5 Research Administration shall provide pricing for services to Investigator on request. Any exceptions to the set rate must have RACC approval.

3.6 All services related to a research project shall be provided at a fair market value rate.

3.7 RACC will use the following in the establishment of the fair market value:

3.7.1 Texas Health contracted rates with managed care companies,

3.7.2 Texas Health pricing provided to uninsured patients who have ability to pay,

3.7.3 Other data that may be deemed appropriate in establishing fair market value for the requested hospital test or service.

3.8 If the Research Investigator is designated as the payee for all study activities and the study sponsor has established a contracted price for the specific hospital service, the hospital must contract with the researcher to provide the requested hospital service(s) at a price that is no less than the price established by the sponsor. If the price for the specific service established by the sponsor is less than or equal to the approved rate, the approved rate will be used. The budget that is part of the Clinical Trial Agreement is required to be shared with Research Administration to verify the price established. Other items listed in the budget may be redacted prior to providing budget to Research Administration.

3.9 Standard of care services (i.e., services that are a covered benefit and properly payable by insurance companies or other payers) provided to a research subject will be billed to payers in accordance with normal billing practices. Billing practices will be consistent with normal hospital billing practices and the billing requirements for patients enrolled in a clinical research study.

3.10 Services that are part of a research study in which Texas Health is defined as engaged must receive HRPPO approval and Institutional Review Board (IRB) approval prior to initiating any parts of the study and any services being provided.

3.11 Services that are standard of care services provided by the Texas Health hospital may be provided by the Texas Health hospital as a commercial service if Texas Health is not deemed as otherwise engaged in the research project.

3.12 Services that are determined to constitute that they will solely be provided to the Principal Investigator on a commercial basis and does not constitute Texas Health engaged human subject research, does not require review and approval by the Texas Health Human Research Protection Program Office (HRPPO).

4.0 Policy Guidance:

4.1 The Principal Investigator is responsible for requesting any desired service to be performed by a Texas Health entity department through the Research Administration office.

4.2 Requests for determination of service category, pricing and initiation of a Purchase Service Agreement should be made to THRResearch@texashealth.org.

5.0 Definitions:

5.1 A Service - Is considered a commercial service(s) (a non-Texas Health engaged study) when:

5.1.1 The research service would not otherwise be conducted at a Texas Health entity; and

5.1.2 The research does not otherwise involve Texas Health employees or agents (e.g., as co- or sub-investigators, as study coordinators, in planning or analysis, or receiving publication credit) or in which Texas Health is defined as engaged; and

5.1.3 The commercial project is genuinely non-collaborative, meriting neither professional recognition nor publication privileges; and

5.1.4 The commercial service(s) adheres to commonly recognized professional standards for maintaining privacy and confidentiality.

5.2 Fair Market Value - Is defined as a rate that Texas Health would charge for the service provided to its other payors and customers.

5.2.1 This rate shall be calculated based on a percent of Texas Health's ChargeMaster listed charge. This percent of the rate shall be set by the Research Activities and Compliance Committee (RACC).

5.3 Standard of Care Services - Are the services that would be provided as part of the patient's care if the patient was not participating in the research study.

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

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

5.4.2 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

5.4.3 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

5.4.4 The subject is consented to participate in the study while a patient at a Texas Health entity; or

5.4.5 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 Related Documentation and/or Attachments:

8.1 Attachment A - Research Special Admission Form

8.2 HRPP - THR System Policy

8.3 Research Engagement - THR System Policy

8.4 Research Contracts - 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.

Attachment A

Affix Patient Label Here
"Hospital Sticker" OR

Acct#_____

RESEARCH SPECIAL ADMISSION FORM

*****PI/Coordinator Requirements*****

1. **Email this completed form and signed ICF to Research Admin: threresearchadministration@texashealth.org**
2. **Affix patient label sticker to each ICF page and place in patient chart**
3. **Notify Research Admin of any deviations from this form**

Instructions:

- Check correct visit and hospital
- Write date and time procedure was performed
- Comment if there were any deviations from this form

The following patient enrolled on a clinical trial and admitted to a THR facility (inpatient or outpatient):

Date of Consent:_____ Date of Service: _____

Patient First Name:_____ Patient Last Name: _____

Patient Study Number: _____ Patient Date of Birth: _____

Protocol Name & IRB Nbr: NCT**:**

THE BELOW IS FOR PROCEDURES/TESTS/SERVICES PERFORMED AND THAT NEED TO BE HANDLED BY RESEARCH ADMINISTRATION. ONLY CIRCLE IF THEY OCCURRED. IF THEY DID NOT OCCUR, DO NOT CIRCLE. IF THEY DID OCCUR, BUT BY A DIFFERENT PROVIDER, PLEASE NOTE WHO PROVIDED THE SERVICE (THIS SHOULD BE AVOIDED AS THERE ARE MAJOR IMPLICATIONS DUE TO THIS DEVIATION).

Visit: __ Implant

Hospital: __

Procedure - CDM	Coding	Qty	Screening/ Randomization	N/A	Date/Time/Comments

I, the Investigator/Coordinator, attest that only the above noted protocol required items were performed, and in accordance with the study coverage analysis. If there are any changes from the above, I agree to notify Research Admin within 24 hours of the change.

_____
Investigator/Coordinator (Sign and Print)

Date _____

****Required For All W9 Completions****

Email: _____

Phone: _____

INTERNAL USE ONLY

___ CBO Code Request 010, CC30

___ NCT#

___ DX V70.7/Z00.6

___ Patient ICF and HIPAA viewable in EMR

___ Patient Added to CTMS by Research Admin