



PROPOSAL FOR RESEARCH PROTOCOL APPROVAL

Attach IRB UTHSCSA Form A-C, D-H, I-K, O, P, R, and Q as Applicable

All boxes on the proposal must be filled out. Place N/A on sections that do not apply.

		Date
Investigator (Name, Degree, Department, Provider Number)	Phone Number	Fax Number

E-mail Address

Co-Investigator (Name, Degree, Department, Provider Number)	Phone Number	Fax Number
Study Coordinator	Phone Number	Fax Number

E-mail Address

Protocol Title
Short Title * <i>Please limit to 24 characters</i>
Study Purpose * <i>Please limit to 95 characters</i>

IRB Number	IRB Expiration Date	Projected Start Date In UHS Facilities	Projected End Date In UHS Facilities	# Pts from UHS Facilities

I. Requested Institutional Support:

Request RECRUITMENT ONLY APPROVAL—Study being conducted at Non-UHS

Attach UTHSCSA IRB

A. List clinical sites/department (s) impacted by this research study for Recruitment.

B. List clinical sites/department (s) impacted by this research study for Enrollment.

C. List clinical sites/department (s) impacted by this research study for Study.

D. List clinical sites/department (s) impacted by this research study for Follow-up.

E. Describe implementation plan for in-service and education regarding protocol for UHS staff and all departments affected or listed above.

List all procedures (i.e. spinal tap, biopsy, catheter placement, etc.) required by the protocol. Indicate procedures required solely for study purposes. In each category, please specify the **number** per patient and **who will pay** the associated charges. # - indicate total number of procedures to be completed as part of the study (e.g. 2 per subject x 30 subjects = 60 tests).

*See fee schedule on research webpage (http://www.universityhealthsystem.com/Research/Research_Department_Home.htm) if procedures not listed contact Research department (Joan.Thomas@uhs-sa.com).

LIST PROCEDURES REQUIRED SOLELY FOR STUDY PURPOSES FROM RESEARCH FEE SCHEDULE		REQUIRED SOLELY FOR STUDY PURPOSES Facility – UH; UHCD; MED; CLINIC, etc.		
Procedure and CPT Code	#	Location	Paid by	

A. Will involvement require any adjusting or resetting of equipment for the research study? Yes No

B. Have Sunrise orders been completed? Yes No

V. Pharmacy Support Information:

IND Number Attach UTHSCSA IRB Form O, Form O-1, Form O-2, Form S as applicable

Attach Form BCHD #7-516

All Research protocols involving investigational drugs and devices must be reviewed and approved by UHS pharmacy

Will University Health Pharmacy services be required for the study? Yes , If Yes which pharmacy? No

University Hospital University Health Center Downtown University Center for Community Health

Other: _____

If P.O. medications will be involved, who will be tracking the information?

Please describe expectations for utilizing pharmacy services:

Please list all medications required by the protocol, and the accompanying information

Medication Name	Provided by	Paid by	Medication Name	Provide by	Paid by

Will investigational drug(s) be used? Yes , If yes _____ No

Attach UTHSCSA IRB Form P

Investigational Drug/Device Data Sheet (BCHD #7-516) for each drug/device to be used must be submitted along with the following information: (if the drug/device is not investigational the following information must still be provided)

Drug/Device will be stored by	Will be dispensed by (M.D. or Pharmacist)	Records will be maintained by

A. Who will be tracking your device? Contact #

VI. Data Safety Monitoring Plan: Attach IRB Form R for monitoring plan

- A. Does the IRB classify your study as minimal risk? Yes No
-What phase is your study in? I I/II II II/III III III/IV
- B. Does your study require a Study Monitor or Representative to oversee this study? Yes No
- C. Will the study Monitor/Representative need access to electronic medical records? Yes No
- D. Will the study Monitor/Representative need to make site visits with pharmacy? Yes No

E. Attach UTHSCSA IRB Form R

If you answered YES to any of questions B, C, and D:

Reference Research Webpage Monitor form

http://www.universityhealthsystem.com/Research/Research_Department_Home.htm

- 1) An appointment must be set up with the Research Pharmacist prior to a visit
- 2) An appointment must be set up to view hard copy and electronic medical records

**Allow 3-5 days for the electronic medical record authorization. Badges for monitors will be provided to the coordinator at the time of study approval.*

**Allow 5 business days for the process of computer access requests*

VII. Support Services Information:

The following support services are requested for support of the study:

- A. Information Service (Access to Information Systems at UHS requested for Staff) Yes No
- B. Pt Business Service (Billing Information) Yes No

VIII. Research Committee Oversight:

Abstract: Attach IRB Form C or attach Form C Abstract Yes No

IX. Was conflict of Interest disclosed at UT IRB? Attach Form X if Yes Yes No

Keywords: (minimum 3, maximum 6. use MeSH (Medical Subject Headings) terms only. Enter one term per line.)

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|----------|----------|
| 1) _____ | 4) _____ |
| 2) _____ | 5) _____ |
| 3) _____ | 6) _____ |