

Tulane University Hospital & Clinic  
**Research Protocol Approval Process**

If this protocol or recruitment is to be conducted at Tulane University Hospital & Clinic,  
*approval must be obtained from the TUHC Administration  
before study participants can be enrolled.*

**FOR EACH STUDY PLEASE SUBMIT THE FOLLOWING TO:**

Carol Carach, TUHC Medical Affairs HC-63 (588-2383; carol.carach@hcahealthcare.com)

- Protocol
- Protocol Summary
- IRB approved Consent
- IRB approval letter
- Meditech Client/Study Addition form and Meditech Charge Form\* if applicable  
*authorized by all relevant departments*
- TUHC Investigational Study Questionnaire

Terry Moore, FPP Business Office, TW-28 (588-2300; terry.moore@hcahealthcare.com)

- Protocol Summary
- IRB approved Consent
- TUHC Investigational Study Questionnaire

\*The Meditech Charge Form must be routed by the study coordinator to each TUHC department that will be providing services/supplies/space to the study. Departments will provide CPT Codes, 6 Digit Billing Codes, descriptions and fees which are a percentage of the current regular charges. The Department Director/Manager approval must be documented by signature in the relevant section on the Meditech form.

**TUHC RESEARCH COORDINATOR WILL:**

- verify individuals providing patient care are credentialed at TUHC for the procedures they will be performing within the facility
- clarify billing/pricing for each procedure
- request any necessary additional information
- route the study to appropriate Hospital Administration for review and approval
- forward copies of the completed Meditech forms to TUHC Business Office for account activation if applicable
- notify PI/Study Coordinator of approval by letter

**TUHC BUSINESS OFFICE WILL:**

- notify the PI, Study Coordinator, relevant TUHC departments, and Hospital Administration that the study account has been activated.

**THE PI/STUDY COORDINATOR WILL:**

- Identify study patients to scheduling staff when scheduling appointments and provide study account number if applicable.
- Medicare? – procedure for Medicare pts is pending at this time
- Identify study patients to hospital registrars and provide study account number if applicable. If services billed to patient insurance/patient and services billed to study will occur on same day two registrations will be necessary.
- Identify charges to appropriate TUHC staff that are billed to study or to patient insurance/patient
- Be responsible for obtaining the signed consent form and placing in the patient's medical record at the time of enrollment.
- Submit protocol and/or consent revisions (with revisions highlighted) and IRB approvals promptly to TUHC Medical Affairs
- Submit IRB Continuing Review Approval letters promptly to TUHC Medical Affairs
- Notify Carol Carach, TUHC Medical Affairs immediately of any research related adverse event at TUHC