# Enhanced Coordination of Clinical Trials

*between*

Tulane University ("TU") and
Tulane University Hospital & Clinic ("TUHC")

Coordinator Training

# Objectives

- This presentation provides an overview of :
  - The respective roles of TU and TUHC regarding research occurring at TUHC
  - The purpose, scope and application of the Master Clinical Trial Affiliation Agreement ("Contract") and study-specific work orders
  - The process for obtaining a TUHC account number

# What is the Contract?

- The Contract is an agreement between TU and TUHC that:
  - Expedites all TU clinical trials conducted in a TUHC setting (i.e., TUHC's downtown hospital & Lakeside Hospital)
  - That are conducted after June 26, 2008
- The Contract addresses the respective duties & obligations of TU and TUHC regarding:
  - Study review & approval
  - Contracting authority
  - Services to be performed (as documented in a study-specific work order)
  - Predictable pricing for TUHC services, including a uniform process for billing & compensation
  - Indemnification

# Study Review & Approval

- TU's IRB serves as TUHC's IRB of record, which means that:
  - TU's IRB is responsible for review & approval of all human subjects research protocols and related informed consents conducted at TU and TUHC
  - This includes both initial review and continuing review

# Contracting Authority


*For each study to be conducted in a TUHC setting:*

- Then
  - Ordinarily, a sponsor would separately contract with TU and TUHC for clinical trials research. This would result in duplicative negotiations, lengthy delays & lack of coordination.
  - The Contract resolves these challenges.
- Now
  - For each clinical study to be conducted in a TUHC setting, TU (through ORA) contracts with the study sponsors on behalf of TU and TUHC to:
    - Obtain research funding; and
    - Executes necessary sponsor research agreements
  - TU and TUHC then sign a study-specific work order

# When are the Work Order Requirements Triggered?

- Does the activity require TUHC to provide services, supplies and/or facilities to TU at either TUHC's downtown or Lakeside hospitals?
  - ❑ Yes
  - ❑ No
- Does the activity involve (a) human subjects research (including but not limited to clinical trials); and/or (b) medical records, either of which will take place at TUHC's downtown or Lakeside hospitals?
  - ❑ Yes
  - ❑ No

If yes, then the arrangement very likely needs a work order between TU and TUHC.

# Scope of Services Under Work Orders

- TUHC is TU's subcontractor for hospital-based research
- Each study-specific work order between TU and TUHC should describe:
  - Services of TUHC investigators & personnel
  - Provision of TUHC supplies & equipment
  - Use of TUHC facilities
- Relevant Forms
  - Meditech Client/Study Addition Form (Attachment "B")
  - Meditech Charge Form (Attachment "C")
  - Investigational Questionnaire (Attachment "E")

# Handouts

- TU Documents:
  - 7-Step Process for Issuing Work Orders (Attachment "A")
- TUHC Documents:
  - Meditech Client/Study Addition Form (Attachment "B")
  - Meditech Charge Form (Attachment " C")
  - Master Charge List (Attachment "D")
  - Investigational Questionnaire (Attachment " E")
  - ORA Checklist for Initiation of Study Agreement Involving Human Subjects (Attachment "F")

# PI/Coordinator Submission of Required Information

***Initial Review: 2-Track Process***

- **Submit to IRB**
  - Initial study application to Tulane's Biomedical IRB consistent with the IRB's applicable policies

- **Submit to ORA**
  - ORA routing sheet
  - Protocol and/or Summary
  - Draft sponsor agreement for proposed study (provide electronic copy as soon as available)
  - Draft informed consent form and assent (if applicable)
  - Final study budget. No right of Hospital to review/approve study budget (unless PI is TUHC employee)

For additional assistance, see
Process for Issuing Work Orders (Attachment "A")

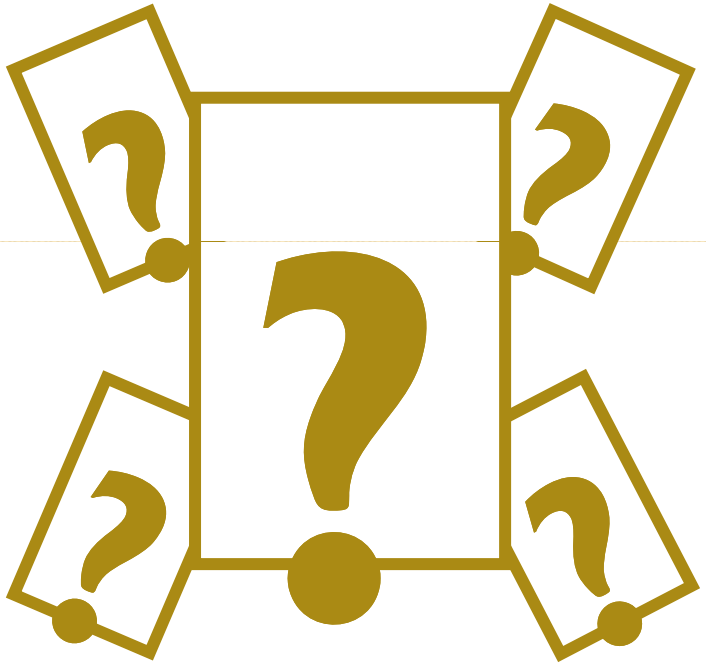
# PI/Coordinator Submission of Required Information

***Continuing Review: 2-Track Process***

- **Submit to IRB**
  - Continuing review application to Tulane's Biomedical IRB consistent with the IRB's applicable policies
- **Submit to TUHC**
  - IRB re-approval letter

# Questions

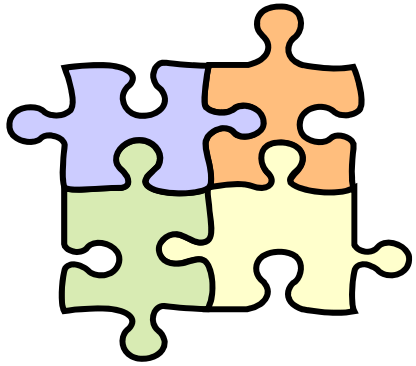
- TU contacts:
  - Verna Lee (ORA) at
    - 504-988-6437
    - vernalee@tulane.edu
- TUHC contacts:
  - Tammy Friloux at
    - 504-988-5410
    - tammy.friloux@hcahealthcare.com
  - Todd LaCaze for financial issues at
    - 504-988-7103
    - Todd.lacaze@hcahealthcare.com



# Billing & Compensation

- TU bills & collects from sponsor all study-related services, both for TU & TUHC
- TUHC must bill TU for study services (per work order terms)
- TUHC cannot bill any third party payor (or subject) for study services furnished by TUHC or its providers under a work order
- Rates:
  - TU will reimburse TUHC pursuant to TUHC's posted fee schedule (see Attachment "D"), as updated annually
  - TU will reimburse TUHC based on reported TUHC investigator effort and documented charges

# Clinical & Procedure Codes



- Duties of the PIs and coordinators:
  - Review protocol to identify hospital based items & services (e.g., document via superbill)
  - Review TUHC Master Charge List (Appendix "D") to determine appropriate code for each item/service
  - Document correct coding on TUHC's Meditech Charge Form (see Attachment " C")
- Proper coding is not a simple task! The PI ultimately is responsible for correct coding. Consult with TUHC departments (e.g., lab, pharmacy or imaging) to resolve coding questions.