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?

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

<table>
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<th>Then</th>
<th>Now</th>
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| - 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. | - 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”)

![Image of pills and pill bottle]

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2. Each study-specific work order between TU and TUHC should describe:
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   - Provision of TUHC supplies & equipment
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   - Relevant Forms:
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     - Meditech Charge Form (Attachment “C”)
     - Investigational Questionnaire (Attachment “E”)

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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

<table>
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<tr>
<th>Submit to IRB</th>
<th>Submit to ORA</th>
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<tbody>
<tr>
<td>◦ Initial study application to Tulane’s Biomedical IRB consistent with the IRB’s applicable policies</td>
<td>◦ ORA routing sheet</td>
</tr>
<tr>
<td>◦ Protocol and/or Summary</td>
<td>◦ Draft sponsor agreement for proposed study (provide electronic copy as soon as available)</td>
</tr>
<tr>
<td>◦ Draft informed consent form and assent (if applicable)</td>
<td>◦ Final study budget. No right of Hospital to review/approve study budget (unless PI is TUHC employee)</td>
</tr>
</tbody>
</table>

For additional assistance, see Process for Issuing Work Orders (Attachment “A”)
## PI/Coordinator Submission of Required Information

**Continuing Review: 2-Track Process**

<table>
<thead>
<tr>
<th>Submit to IRB</th>
<th>Submit to TUHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Continuing review application to Tulane’s Biomedical IRB consistent with the IRB’s applicable policies</td>
<td>- IRB re-approval letter</td>
</tr>
</tbody>
</table>
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.