PROCESS FOR OBTAINING APPROVAL TO CONDUCT A CLINICAL TRIAL AT TULANE UNIVERSITY AND/OR TULANE UNIVERSITY HOSPITAL & CLINIC ("HOSPITAL") (TUHC)

Step #1 IRB Application - Submit Sponsor Research Agreement to SPA- Determine Hospital Role in Study:

Note: Steps #1 & 2 processes are not sequential and should be undertaken simultaneously to the extent possible.

- Tulane's PI/Coordinator submits a new study application to Tulane's University's Biomedical IRB consistent with the IRB's applicable policies:
  - If study involves drugs, contact Hospital Research Pharmacist
- For studies that are industry funded, the PI/Coordinator submits to the Sponsored Projects Administration Office (SPA) the following:
  - SPA routing sheet (revisions are made often, obtain the current version from the SPA Website)
  - 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)
- If study will utilize Tulane University Hospital and Clinic's (TUHC) [inclusive of TUHC's clinics, Lakeside Hospital] facilities, personnel, services or pharmacy. (This bullet is not applicable to "Medical Record Review only" studies.) PI/Coordinator submits the following forms to the TUHC Representative for Pre-Review:

  Study Protocol
  Hospital Forms found at http://tulane.edu/som/ctu/training.cfm

  - TUHC Representative reviews forms to assess whether additional information needs to be exchanged
    - If needed TUHC Representative will schedule Planning Meeting with PI/Coordinator and necessary TUHC personnel (including the Pharmacist if needed) to:
      - provide preliminary information about study to TUHC
      - determine what TUHC resources will be required and the associated CPT code and costs.
      - determine credentialing requirements
      - determine training requirements.

Step #2 Clinical Trial Agreement Negotiation (only applicable to funded studies).

- PI/Coordinator determines cost (including indirect costs) to conduct study and negotiates budget with Sponsor
  - PI/Coordinator provides final budget to SPA
  - Coordinator sends SPA routing sheet (revisions are made often, obtain the current version from the SPA Website).
- SPA negotiates sponsored research agreement language.
  - SPA executes sponsor awards and notifies IRB when award is fully executed

Step #3 IRB Approval of Protocol and Notification:

- Tulane's IRB notifies the PI/coordinator of approval. IRB approval letter will be accessible to PI/coordinator through IRBnet.

Step #4 Department Sends SPA Documents for Hospital Work Order: The PI/Coordinator submits to SPA the following:

- Department cover letter, to specify department approval, listing of documents submitted and clarify study type (e.g., all procedures paid for by sponsor versus all procedures paid for by subject/subject's payor versus mixed process) (Coverletter is optional)
- IRB-approved protocol (only if not previously submitted or if changed since submitted in Step 1 above)
- IRB-stamped approved informed consent/assent and HIPAA consent (if applicable)
- IRB stamped approval letter

[1]Tulane Hospital and Clinic includes Tulane University Hospital, Lakeside Hospital and Tulane Hospital for Children and all affiliated clinics

- TUHC Forms (forms are completed in step 1 and revised as needed per pre-review meeting)
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Step #5 SPA Submits Work Order to Hospital:

- The SPA administrator will submit the Work Order to TUHC Representative.

Step #6 Hospital Reviews and Signs Work Order: This step should be completed within five (5) business days.

- TUHC Representative will review package and contact PI/Coordinator if additional information is required. Once packet is acceptable, TUHC representative forwards to senior management for final review and execution.

Step #7 Hospital Approves Study and Establishes Hospital Study Procedure Account: Within 2 days of TUHC's signature of the work order, the Hospital will:

- Provide copy of executed work order (excluding appendices) to SPA administrator
- Enter study into Meditech Library
- Submit required documentation to TUHC Billing Dept for account setup if applicable
- Email PI/coordinator (cc-SPA) study account number and/or study approval authorization

Step #8: When All Of The Following Have Been Obtained - Commence Subject Enrollment

- For funded projects – the funding contract has been signed by all parties (Tulane, PI and the Sponsor)
- IRB approval has been obtained for the study
- TUHC approval of work order/study has been sent to PI. (Only applicable to studies using TUHC pharmacy, personnel, facilities or services.)
  - All Protocol Required Training of TUHC personnel must be complete prior to enrollment

Other Pertinent TUHC Information for Conducting the Study – Contact TUHC for specifics:

- **TUHC has policy regarding Protocol Training of TUHC personnel who will be involved in the study.**
- **TUHC has procedures for registering study patients for SOC procedures and procedures for registering study patient for study billable procedures.**
- **TUHC has policy on using any equipment (ie equipment loaned by Sponsor or purchased with Study funds) in its Hospital's and Clinics.**
- **TUHC has invoice review policy. PI/Coordinator must review study related bills within 30 days and notify TUHC of any billing errors. TUHC has only 60 days to bill 3rd party payor for service.**

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