BUDGET PROCESS: DETERMINATION SCHEMA

INDUSTRY SPONSORED, INDUSTRY SUPPORTED, UNIVERSITY TO UNIVERSITY, CO-OPERATIVE GROUP OR FOUNDATION SUPPORTED CLINICAL TRIALS

Following Procedure I flow chart

A. PRE-TRIAL:
   o In order to open an industry sponsored, industry supported, university to university or foundation clinical trial at the University of Connecticut Health Center, the following questions must be answered to determine the proposal’s flow through the institution:
     • Does the project involve human subjects?
     • Will the project generate UMG or JDH service charges per patient?

If these questions can be answered “yes”, then the proposal will need to have a Budget Workbook done by staff in the Office of Clinical & Translational Research (OCTR) before an application can be submitted to the IRB. In some instances, the budget may not be fully negotiated but the Budget Workbook, itself, must be complete. If the clinical trial does not generate patient charges, a memo will be sent by OCTR to the Principal Investigator (PI) and the IRB stating that no Budget Workbook is needed.

B. BUDGET WORKBOOK:
   • OCTR staff complete all phases of the Budget Workbook with PI, Study Coordinator and/or Department or Program Administrator.
   • Items and services are delineated as Protocol Induced Costs (PIC) or Routine Clinical Care (RC)
   • T&E is delineated for dedicated research staff
   • If the budget is not adequate to cover study expenses, OCTR commences budget negotiations and/or PI provides additional funding source.

C. INITIATION OF ROUTING:
   • Upon OCTR completion of the Budget Workbook, the PI approves the budget and signs the Internal Proposal Review Form (IPR), thereby initiating the routing process.
   Routing sheet is then signed by
     ♦ PI’s Department chair
     ♦ Co-Investigator (if applicable)
     ♦ Co-Investigator’s Department chair (if different department than PI)
     ♦ Dean
     ♦ Director, Sponsored Program Services

D. CONTRACT

Contract negotiations continue in parallel with the budget preparation and the routing, as shown on the preceding flow chart for Procedure 1

   o Contract negotiations may be ongoing at the time of IRB submission.
E. **IRB SUBMISSION**

- Study Coordinator may now submit a complete initial application packet to the IRB per institutional guidelines, and including the memo certifying that a *Budget Workbook* is complete or budget negotiations are ongoing.

F. **IRB APPROVAL PROCESS**

- IRB approves protocol – contingent approval.
  - Contract can be signed by PI, institutional signatory and sponsor upon IRB approval or IRB contingent approval of the protocol. Copy of fully executed contract sent to IRB for final approval.
  - Upon final IRB approval, copy of fully executed contract sent to PI and Department Program Administrator.
  - Study cannot open until there is a fully executed contract and final IRB approval.

Please see Procedure II for outline of Trial Startup.