BUDGET PROCESS: DETERMINATION SCHEMA
FEDERAL OR AWARDS IN RESPONSE TO A PUBLIC SOLICITATION

Following Procedure Ia flow chart

NOTE: Clinical Trials in this section may be Federal or Awards* in response to a public solicitation. (Federal and State contracts will be addressed on an individual basis).

A. PRE-TRIAL:
   - In order to open a Federal or Awards in response to a public solicitation 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?
     - Does the clinical trial generate UMG or JDH service charges per patient?

If these questions can be answered "yes", then the proposal will require a Budget Workbook completed by the Office of Clinical and Translational Research (OCTR). If the clinical research does not generate patient charges, a memo stating that no Budget Workbook is necessary will be completed by OCTR and sent to the Principal Investigator (PI) and the IRB.

B. BUDGET WORKBOOK:
   - OCTR staff complete all phases of the Budget Workbook with the 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 all dedicated research staff
   - If the budget is not adequate to cover study expenses, it is returned to the PI to adjust original budget and/or identify other support

C - D. ROUTING:
   - If the study requires a Budget Workbook, the OCTR routing sheet titled Internal Proposal Review Form (IPR) must be used (see Routing Forms).
   - PI routes summary of proposal, the approved budget and appropriate Routing Sheet(s) to:
     - Department chair
     - Any co-investigator Department chair (if different than the PI’s department)
     - Dean
     - Director, Sponsored Program Services

E. SUBMISSION OF GRANT**
   - Proposal submitted to outside funding agency
   - If approved for funding, OCTR should be notified of amount of final award
   - Project can now be submitted to the IRB
F. IRB SUBMISSION/APPROVAL PROCESS:
   o The PI and Study Coordinator prepare and submit a complete IRB application packet per institutional guidelines, including the approved budget, to the IRB.
     • Application Approved: A copy of the PI’s approval letter will be sent to OCTR and SPS.
     • Application Deferred: Study will be returned to PI for changes and re-submission.
     • Application Approved Contingent: Study cannot open until contingencies are met.

G. TRIAL COMMENCEMENT:
   o IRB notifies PI/study staff, SPS and cc’s OCTR when study is approved.

Please see Procedure II for outline of Trial Startup.

*Appendix I:
The following represent the main types of federally funded grant awards and projects that will continue to be negotiated by the Sponsored Program Services (SPS) at the University of Connecticut Health Center. See the following link for a listing of all NIH grant mechanisms.  
http://grants.nih.gov/grants/funding/funding_program.htm

Research Grants:
   o R01 – NIH Research Project Grant Program
   o R03 – NIH Small Grant Program
   o R13/U13 – NIH Support for Conferences and Scientific Meetings
   o R15 – AREA: NIH Academic Research Enhancement Award
   o R21 – NIH Exploratory/Development Grant Award
   o R34 – NIH Clinical Trial Planning Grant
   o R41/R42 – STTR: Small Business Technology Transfer
   o R43/R44 – SBIR: Small Business Innovative Research
   o R56 – NIH High Priority, Short-Term Project Award
   o U01 – Research Project Cooperative Agreement
   o K99/R00 – NIH Pathway to Independence (PI) Award

Career Development Awards (K series)

Research Training and Fellowships (T & F series)

Program Project/Center Grants
   o P01 – Research Program Project Grant
   o P02 – Exploratory Grant
   o P30 – Center Core Grants
   o P50 – Specialized Center Grants

Resource Grants
   o R24 – Resource-Related Research Projects
   o R25 – Education Projects
   o X01 – Resource Access Program
Trans-NIH Program

- BISTI – Biomedical Information Science and Technology Initiative
- Blueprint – NIH Blueprint for Neuroscience Research
- Diversity Supplements
- Administrative Supplements
- ES I- New and Early Stage Investigators Policies
- GWA S- Genome-Wide Association Studies
- NIH Common Fund – NIH Roadmap for Medical Research
- OppNet - NIH Basic Behavioral and Social Science Research Opportunity Network
- PECADE – Presidential Early Career Award for Scientists and Engineers
- Stem Cells

** If Grant is submitted before the Budget Workbook is done a Budget Workbook will have to be completed before the IRB submission