DENTAL BUDGET PROCESS: DETERMINATION SCHEMA INDUSTRY SPONSORED, INDUSTRY SUPPORTED, UNIVERSITY TO UNIVERSITY, CO-OPERATIVE GROUP OR FOUNDATION SUPPORTED DENTAL CLINICAL TRIALS

A. Does project involve Human Subjects?
   - Yes
     - Will the project generate medical service charges in UMG and/or JDH or dental charges in Axium?
       - Yes
         - PI, Study Coordinator, Department/Program Administrator, and OCTR complete budget workbook
         - Revised budget resubmitted
       - No
         - Request Budget Workbook memo from OCTR
         - Normal Routing
   - No
     - Normal Routing

B. PI, Study Coordinator, Department/Program Administrator, and OCTR complete budget workbook
   - Is budget adequate to cover study expenses?
     - Yes
       - Routing Sheet signed by PI, Co-PI, Dept. Chair(s), Director of DCRC & Exec. Admin. OCTR
       - Contract negotiations ongoing
     - No
       - OCTR commences budget negotiations and/or PI provides additional funding source

C. PI approves budget
   - Submit IRB application and consent form to IRB

D. IRB Review Study
   - Deferred
     - PI & research staff meet contingencies or address deficiencies
     - Resubmit to IRB
   - Approved
     - Submit Contingencies
     - Approved Contingent**
     - Contract signed by PI, UCHC Associate VP RAF & Sponsor
   - IRB applications approved with contingencies may be signed while contingencies are addressed. Study cannot open until there is a fully executed contract and final IRB approval.

E. Contract to OCTR and contract negotiations begin in parallel

F. Copy of fully executed contract sent to IRB for final approval. Upon final IRB approval, copy of fully executed contract sent to PI & Dept. Program Administrator

11/5/2013, 10/29/15
Dental Budget Process: Determination Schema Industry Sponsored, Industry Supported, University to University, Co-operative Group or Foundation Supported Dental Clinical Trials