UConn Health Office of Clinical and Translational Research (OCTR)
QUICK FACTS

CONTRACTS

Clinical trials at UConn Health cannot commence until a contract has been fully negotiated, approved and executed and the clinical trial has received final IRB approval.

TYPES:

- CLINICAL TRIAL AGREEMENTS (CTA)
- CONFIDENTIALITY DISCLOSURE AGREEMENTS (CDA)
- CONTRACT AMENDMENTS
- LETTERS OF INDEMNFICATION (LOI)

OCTR DOES NOT NEGOTIATE:

- FEDERALLY FUNDED INVESTIGATOR INITIATED AGREEMENTS*
- CLINICAL TRIALS OR CLINICAL RESEARCH IN WHICH THE PRIME AWARD IS IN RESPONSE TO A PUBLIC SOLICITATION

**In this instance, the proposals will be negotiated by the staff in Sponsored Programs Services (SPS)*

ROUTING

All grants and contracts require routing. Upon completion of the Budget Workbook, the PI approves the budget, then routing can be submitted.

IF YOUR STUDY HAS A BUDGET WORKBOOK, YOU MUST USE THE INTERNAL PROPOSAL REVIEW FORM (IPR):

CLINICAL TRIALS

- NON-FEDERAL INVESTIGATOR INITIATED INDUSTRY SUPPORTED
- INDUSTRY SPONSORED
- UNIVERSITY TO UNIVERSITY
- CO-OPERATIVE GROUP
- FOUNDATION SUPPORTED
- WITHIN A FEDERAL GRANT
- PRIME AWARD THAT IS IN RESPONSE TO A PUBLIC SOLICITATION

Forms can be obtained in the Forms Section of the website

CLINICAL TRIALS BANNER ACCOUNTS

Newly approved clinical trials will be assigned a fund number in the University's Banner accounting system. This fund will be set-up and administered in OCTR in order to track study related financial activity.

- BANNER FUND SET-UP
- INITIAL BUDGET AND SUPPLEMENTS
- IPAS OR NO COST EXTENSION
- SPONSOR PAYMENTS
- STUDY RELATED EXPENSES

BUDGET WORKBOOK

A budget workbook must be done by OCTR for all research studies that produce Institutional charges before submission to the IRB for review. It allows the PI to realistically assess the cost of doing clinical trials, it separates Routine Care Costs (RC) from Protocol Induced Costs (PIC) ensuring PI and institutional compliance with state and federal regulations.

SCHOOL OF MEDICINE AND SCHOOL OF DENTAL MEDICINE

DOCUMENTS NEEDED:

- ✓ STUDY PROTOCOL, INCLUDING SCHEMA OF PATIENT EVENTS
- ✓ STUDY BUDGET, AS PROPOSED BY SPONSOR
- ✓ INFORMED CONSENT FORM OR SPONSOR TEMPLATE
- ✓ COMPLETED OCTR PRELIMINARY BUDGET INFORMATION PACKET*

**Can be obtained in the Forms Section of the website*

BUDGET INITIATION MEETINGS

For all studies which require a Budget Workbook, a budget initiation meeting is scheduled when final IRB approval is issued. The meeting should occur prior to the enrollment of the first study participant, but may occur due to scheduling conflicts within two weeks of the opening of the study. It is necessary that the PI attend and strongly recommended, that the study coordinator, department administrator and/or billing coordinator attend the budget initiation meeting.

HEALTHONE RESEARCH – NEW STUDY BUILD

Call HealthOne Call Center – x4400, Option 1
Request new RESEARCH study to be built in Epic
Send completed New Study Submission form and Help Desk ticket number to HealthOneResearch@uchc.edu
Form can be obtained in the Forms Section of the website

OCTR CONTACTS:

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