UCONN HEALTH

POLICY NUMBER 2006-11

November 19, 2013

POLICY: CONTRACT NEGOTIATIONS FOR INITIATION OF CLINICAL RESEARCH AND/OR CLINICAL TRIALS NEGOTIATED BY STAFF IN THE OFFICE OF CLINICAL & TRANSLATIONAL RESEARCH

PURPOSE: To ensure that contract negotiations with sponsors and/or funding agencies relative to clinical research/trials to be opened at UConn Health and accomplished through the Office of Clinical and Translational Research (OCTR) follow all relevant institutional policies and procedures.

SCOPE: This policy applies to clinical research and/or clinical trials involving human subjects that are sponsored and/or supported by:

- The pharmaceutical/biotech industry,
- University to university sub-contracts,
- Co-operative groups
- Foundations

This policy does **not** apply to:

- Investigator Initiated federally sponsored clinical research/clinical trials
- Clinical research/clinical trials in which the Prime Award is in response to a public solicitation (e.g. Request for Information (RFI), Request for Application (RFA), Funding Opportunity Announcement (FOA), Connecticut Institute Clinical and Translational Science (CICATS), Komen foundation)*

In these instances, the proposal will be negotiated by the staff in the Office of Research and Sponsored Programs (ORSP) **

POLICY STATEMENT:
Staff in the OCTR designated to negotiate contracts shall, with input from the Principal Investigator (PI), the Attorney General's Office, the Human Subjects Protection Office and the Office of the Associate Vice President for Research Administration, negotiate all contracts for clinical research/clinical trials involving human subjects to be opened at UConn Health. This does not include investigator initiated federally sponsored clinical research/trials or projects in which the Prime award is in response to a public solicitation.

* see Appendix 1 for list of federally funded grant awards and projects

** all clinical research/trials budgets that include John Dempsey Hospital, University Physicians and or Dental charges must always be submitted to the OCTR in order for a budget workbook to be completed.

The Budget Workbook, delineating all costs and revenue, will be completed by appropriate OCTR staff with input from the PI before contract negotiations can be completed. Contracts will not be approved by the Associate Vice President for Research Administration until the clinical research/trial has at least contingent approval by the Institutional Review Board (IRB)

DEFINITIONS:

Clinical Research:

A. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes:
   - Mechanisms of human disease
   - Therapeutic interventions
   - Clinical trials
   - Development of new technologies
B. Epidemiologic and behavioral studies
C. Outcomes research and health services research.[1]

Clinical Trial: A clinical trial is a systematic, organized, prospective intervention study in human subjects that is conducted according to a formal study plan (protocol) and that has measurable efficacy and/or safety-related outcomes that are amenable to statistical analysis. It employs one or more intervention technique(s) including prophylactic, screening, diagnostic, or therapeutic agents, devices, or procedures. It must have approval of the IRB or review with a determination of exemption. Clinical trials are distinguished from other types of clinical research (e.g., behavioral research) that may need IRB approval but do not meet the other criteria of clinical trials.[2]

Principal Investigator (PI): The researcher with overall responsibility for the direction of a research project, grant or contract. A medical professional who is overseeing the treatment of subjects in the clinical trial.

Study Coordinator: The member of the research team, who manages the daily activities of the study, including coordinating the treatment or testing of participants. Study Coordinators are also responsible for such things as, recruiting, screening, and enrolling study participants, as well as ensuring the adherence to Good Clinical Practice.

[1] National Institutes of Health (NIH), panel on Clinical Research 1995

[2] Adapted from Emory University, Association of Academic Health Centers (AAHC), 2004

Sponsor: The entity (e.g., pharmaceutical/ biotech company, co-operative groups private foundation, individual investigator, etc.), that is the originator/author of the clinical research/trial that is being administered by the PI.

Funding Agency: The entity (e.g., pharmaceutical/biotech company, private foundation) that is providing funding for the clinical research/ trial that is being administered by the PI.

Peter Albertsen (Signed) 11/27/13

Peter Albertsen, M.D. **Date**
Associate Dean, Clinical and Translational Research

Frank M. Torti (Signed) 1/2/14

Frank M. Torti, M.D., M.P.H **Date**
Executive Vice President for Health Affairs

New Policy: 6/23/06
Revised: 11/19/13

Appendix I:

The following represent the main types of federally funded grant awards and projects that will continue to be negotiated by the Office of Research and Sponsored Programs (ORSP) 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:

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

Career Development Awards (K series)

Research Training and Fellowships (T & F series)

Program Project/Center Grants

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

Resource Grants

- R24 – Resource-Related Research Projects
- R25 – Education Projects
- 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
- PECASE – Presidential Early Career Award for Scientists and Engineers
- Stem Cells