



University of Connecticut Health Center

POLICY NUMBER 2006-11

June 23, 2006

**POLICY: CONTRACT NEGOTIATIONS WITH
PHARMACEUTICAL/BIOTECH INDUSTRY FOR INITIATION
OF CLINICAL RESEARCH AND/OR CLINICAL TRIALS**

PURPOSE:

To ensure that contract negotiations with sponsors from the pharmaceutical/biotech industry relative to clinical research/trials to be opened at the University of Connecticut Health Center (UCHC) are accomplished through the Office of Clinical and Translational Research (OCTR) following all relevant institutional policies and procedures.

SCOPE:

This policy applies to clinical research and/or clinical trials involving human subjects that are sponsored by the pharmaceutical/biotech industry. This policy does not apply to federal or foundation sponsored clinical research/trials.

POLICY STATEMENT:

Staff in the OCTR designated to negotiate contracts with the pharmaceutical/biotech industry 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 UCHC. The Budget Workbook, delineating all costs and revenue, will be completed by appropriate 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 all contingencies imposed by the Institutional Review Board (IRB) have been satisfied, with the exception of the contingency that a final contract for the study be in place before the clinical trial has been initiated.

[Hyperlink to Budget Workbook](#)

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.

Sponsor: The entity (e.g., pharmaceutical company, National Institutes of Health (NIH), National Cancer Institute (NCI), private foundation, individual investigator, etc), that is the originator and/or financier of the clinical trial protocol that is being administered by the PI.

Bruce M. Koeppen, M.D. 7/27/06
Dean for Academic Affairs **Date**

Peter Albertsen, M.D. 7/27/06
Associate Dean, Clinical and Translational Research **Date**

Peter J. Deckers, M.D. 7/27/06
Executive Vice President for Health Affairs **Date**

NEW POLICY: June 23, 2006

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

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

