

UConn HEALTH

POLICY NUMBER 2006-07

June 23, 2006

POLICY: CLINICAL RESEARCH/TRIALS BUDGET REVIEW

PURPOSE:

To ensure that all Principal Investigators (PI) who participate in human clinical research activities, including clinical trials within UConn Health, complete a Budget Workbook that is compliant with all institutional policies and procedures prior to study contract negotiations and submission of the study to the Institutional Review Board (IRB).

SCOPE:

This policy applies to all clinical research projects involving research induced medical interventions and research-related patient charges generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within UConn Health.

POLICY STATEMENT:

The goal of the Budget Review Process is to allow the investigator, department chair and research administration to make an informed decision regarding institutional participation in a clinical research/trial project. The Clinical Research/Trials Budget Review process ensures that projects comply with institutional policies, as well as state and federal laws and regulations.

Prior to submission of a clinical trial to the IRB for approval, the PI, with the assistance of his/her department administrator and/or study coordinator and in collaboration with the financial staff in the Office of Clinical & Translational Research (OCTR), will prepare a budget including expected revenues from the sponsor and the direct and indirect costs associated with conducting and administering the trial.

[Hyperlink to Budget Workbook](#)

[Hyperlink to Procedures for research study budget approval](#)

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.

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| <u>Bruce M. Koeppen, M.D.</u> | <u>7/27/06</u> |
| Dean for Academic Affairs | Date |
| <u>Peter Albertsen, M.D.</u> | <u>7/27/06</u> |
| Associate Dean, Clinical and Translational Research | Date |
| <u>Peter J. Deckers, M.D.</u> | <u>7/27/06</u> |
| 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