UCONN HEALTH

POLICY NUMBER 2007-06

August 16, 2007

Policy: Clinical Trials Under Contract - Administrative Requirements

Purpose:
To insure that an appropriate written agreement is executed between individuals or entities and UConn Health for services UConn Health provides as part of a sponsored clinical trial. Only a person with institutional signatory authority can sign contracts on behalf of UConn Health.

Scope:
This policy applies to all Principal Investigators (PIs) of sponsored clinical trials undertaken at UConn Health in the inpatient or outpatient setting.

PI (non-paid faculty) - An investigator who is a non-paid faculty member may serve as the PI of a clinical trial at UConn Health if he/she adheres to all the steps outlined below. Additionally, a sub-contract between the PI and UConn Health will be developed to pay for the cost of services rendered by the PI and/or his staff. This sub-contract will be signed by the approved representatives of both entities.

Policy Statement:
A fully executed signed contract must be in place between UConn Health and the project sponsor for all sponsored clinical trials undertaken at UConn Health. Provisions of the agreement will include but are not limited to the scope of the project, a description of services to be provided by UConn Health, budget, payment terms, reporting obligations, and compliance obligations. The agreement must also contain appropriate institutional indemnification, subject injury language, publication and intellectual property provisions.

1. The PI, usually a paid faculty member, will follow all appropriate UConn Health policies and procedures regarding budget preparation, contract negotiations, financial compliance and human subjects' protection as delineated in UConn Health policies and procedures

    - Research Financial Compliance:
      http://octr.uchc.edu.

    - Human Subjects' Protection:
      http://hspo.uchc.edu/investigators/HSPOPolicies.html

2. The contract must contain all criteria necessary to conduct a clinical trial per UConn Health policies.

3. The PI will work with the budget coordinator from the office of clinical and translational research to prepare all budgets using the UConn Health budget workbook. Final contract budgets must be approved according to UConn Health policies.
4. The contract will be negotiated in the usual manner through the office of Clinical and Translational Research (OCTR) according to UConn Health policies and procedures.
5. All monies paid by the sponsor as part of the clinical trial agreement, including facilities and administrative costs, regulatory costs and patient care costs will be paid to UConn Health in the usual manner according to UConn Health policies and procedures.
6. The contract must be fully executed between the sponsor and UConn Health and signed by the approved representatives of both entities before any patients can be enrolled.

Definitions:

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.

Principal Investigator (PI): The researcher with overall responsibility for the direction of a research project, grant or contract. In a clinical trial this person must also be a health professional who is overseeing the treatment of subjects in the clinical trial.

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 Koeppen (signed)	8/21/07
Dean for Academic Affairs	**Date**
Peter Albertsen (signed)	8/21/07
Associate Dean, Clinical and Translational Research	**Date**
Peter Deckers, M.D. (signed)	8/24/07
Executive Vice President for Health Affairs	**Date**

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