

UConn HEALTH

POLICY NUMBER 2009-06

November 20, 2009

POLICY: STABILIZATION OF CHARGES FOR CLINICAL RESEARCH TRIALS

PURPOSE:

To ensure charges for Protocol Induced Research Services in a clinical trial, as quoted to a Principal Investigator from the UConn Health Charge Master at the time of the Budget Workbook, will remain constant for a period of three years, regardless of increases in the UConn Health Charge Master.

SCOPE:

This policy applies to all clinical trials involving research induced medical interventions and research-related patient charges for UConn Medical Group (UMG) professional fees and/or John Dempsey Hospital (JDH) hospital charges generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within the University of Connecticut Health Center.

POLICY STATEMENT:

Charges assigned to Protocol Induced Research Services at the time of the Budget Workbook completion will remain in effect for three years from the date of the study's Clinical Trials BEAN Initiation Form. If a clinical trial requires JDH/UMG Protocol Induced Research Services beyond the three year period, and charges during that period have increased in the UConn Health Charge Master, a new Budget Workbook will be completed and charges will be renegotiated.

DEFINITIONS:

Clinical Research:

Patient-oriented 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
- Epidemiologic and behavioral studies
- Outcomes research and health services research ¹

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

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 measureable efficacy and/or safety-related outcomes that are amenable to statistical analysis. It employs one or more intervention techniques(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

Protocol Induced Research Services:

Items and services that are specifically excluded from the definition of Routine Clinical Services, such as:

- The investigational item or service, itself; *unless otherwise covered outside of the clinical trial*;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial
- Items and services provided solely to determine trial eligibility

Principal Investigator (PI):

The researcher with overall responsibility for the direction of a research project, grant or contract and/or a medical professional who is overseeing the treatment of subjects in the clinical trial.

Budget Workbook:

Electronic tool used by Office of Clinical & Translational Research in conjunction with the study team to realistically assess the cost of doing a clinical trial by identifying, segregating and monitoring study charges.

Peter Albertsen (signed)	12/14/09
_____ Associate Dean, Clinical Research Planning and Administration	_____ Date
Bruce Koeppen (signed)	12/17/09
_____ Dean for Academic Affairs	_____ Date
Cato T. Laurencin (signed)	12/17/09
_____ Vice President for Health Affairs	_____ Date

NEW POLICY: November 20, 2009

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