UCONN HEALTH

POLICY NUMBER 2010-01

July 23, 2010

POLICY: CLINICAL RESEARCH/TRIALS "FACILITY DISCOUNT" FOR HOSPITAL-BASED OUTPATIENT PROGRAMS

PURPOSE:
To ensure that all investigators who see research subjects as part of a Protocol Induced Cost (PIC) in clinical research, including a clinical trial, are not charged a separate John Dempsey Hospital (JDH) facility fee when the PIC research visit is in a hospital-based outpatient facility (e.g., Cardiology and Cancer) within UConn Health.

SCOPE:
This policy applies to all clinical investigators who see research subjects in the outpatient facility of their hospital-based programs; these charges are PIC and charged to the study. The policy specifically includes only the PIC John Dempsey Hospital facility fee for the subject/MD visit. This policy does not apply to other ancillary services within JDH/UMG where PIC facility and professional fees are always charged separately to the study sponsor.

POLICY STATEMENT:
For investigators who participate in human subject clinical research activities, including clinical trials within UConn Health, the goal of this policy is to charge a professional fee only for subjects' PIC visits, as is done when research subjects are seen by investigators in their University Medical Group (UMG) offices. Investigators whose outpatient facilities come under John Dempsey Hospital will not be charged a JDH facility fee for PIC research subjects' visits. This visit will be designated as a "research no charge" visit in the IDX system and will not be charged to the investigator or the research subject or insurance.

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]

[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 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 Institutional Review Board (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.

Investigator: 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 Koeppen (Signed) 8/20/10

Dean for Academic Affairs **Date**

Peter Albertsen (Signed) 8/20/10

Associate Dean, Clinical Research Planning &Administration **Date**

Cato T. Laurencin (Signed) 8/20/10

Executive Vice President for Health Affairs **Date**

NEW POLICY: July 23, 2010

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