UCONN HEALTH

POLICY NUMBER 2006-08

June 23, 2006

POLICY: CLINICAL RESEARCH/TRIALS PATIENT BILLING COMPLIANCE

PURPOSE:

To ensure all patient billing of research-related professional and technical charges done at UConn Health is uniform and compliant with all internal policies as well as all applicable state and federal laws and regulations including, but are not limited to, Medicare and Medicaid and in accordance with contractual obligations to third party payers. [1]

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 the UConn Health.

POLICY STATEMENT:

The goal of the Research Billing Compliance Policy is to ensure identification and generation of accurate, consistent and appropriate billing of patient research-related charges by UConn Health employees.

Standard Operating Procedures

Overview:

Accountability for compliance with laws, regulations and applicable UConn Health policies pertaining to the identification and billing of patient research related charges is ultimately vested with the principal investigator (PI) conducting the research activity. This includes the identification and delineation of Protocol Induced Costs (PIC), and Routine Costs (RC) on a per patient basis for each study before submission to the Institutional Review Board (IRB) for approval.

If a disagreement exists between the PI and the Office of Clinical and Translational Research (OCTR) staff concerning the delineation of services as PIC or RC within a clinical trial, the Associate Dean for Clinical Research & Planning will meet with the PI to resolve the disagreement. If the disagreement is not resolved, the Associate Dean will

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[1] Medicare Coverage Policy regarding Clinical Trials, Final National Coverage Decision (NCD), (September 19, 2000) http://www.hcfa.gov/medlearn/rcfctmed.htm

ask the Chair or Type Two Center Director of the PI's Department to review the services in question in light of the standard medical/surgical practices in the region. The Associate Dean will make the final determination. The PI may appeal the decision(s) to the Hospital Chief of Staff who may either affirm or reverse the decision(s) of the Associate Dean.

Documentation:
In all cases, published Medicare and Medicaid regulations and contract language with third party payers will serve as UConn Health documentation of billing and other claim submission expectations as they apply to research-related charges. In cases of multiple interpretations, vague expectations or contradictory regulatory language, UConn Health will supplement published regulations with UConn Health Research Billing Compliance Policies and Procedures that clearly set forth the UConn Health's expectations.

Employee Reporting:
UConn Health Compliance Program requires all individuals to promptly report any known or suspected violations of laws, regulations, standards, policies and procedures that apply to the UConn Health.

Reporting Compliance Concerns - Policy #2003-33

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.[2]

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

[2] National Institutes of Health (NIH), panel on Clinical Research 1995

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.[3]

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.

(Signed) 11/17/11

Associate Dean, Clinical and Translational Research **Date**

(Signed) 11/21/11

Vice President for Health Affairs **Date**

[1] Adapted from Emory University. Association of Academic Health Centers (AAHC). 2004