



University of Connecticut Health Center

POLICY NUMBER 2006-06

June 23, 2006

**POLICY: EVALUATION OF CLINICAL RESEARCH/ TRIAL FOR
MEDICARE REIMBURSEMENT**

PURPOSE:

To insure that all clinical research/trials are registered in the Office of Clinical & Translational Research (OCTR), and reviewed by the Principal Investigator (PI) in conjunction with financial staff in the OCTR, to ascertain whether the research “qualifies” for Medicare reimbursement under the National Coverage Decision (NCD). If the study qualifies under the NCD, identification of services billable to Medicare and those billable to the sponsor will be delineated.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 University of Connecticut Health Center.

POLICY STATEMENT:

Status of all new clinical research/trials relative to Medicare reimbursement will be determined by the PI and financial staff in the OCTR before a study budget is negotiated, the study is submitted to the Institutional Review Board (IRB), and the contract signed. Prospective certification of the “qualifying status” and delineation of Protocol Induced Costs (PIC), and Routine Costs (RC) will assure that only those studies and charges that meet Medicare specifications for reimbursement will be designated as such.

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

¹ Medicare Coverage Policy regarding Clinical Trials, Final National Coverage Decision (NCD), September 19, 2000) <http://www.cms.hhs.gov/ClinicalTrialPolicies/>

- 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 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.

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Dean for Academic Affairs

7/27/06
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Associate Dean, Clinical and Translational Research

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

³ Adapted from Emory University, Association of Academic Health Centers (AAHC), 2004

NEW POLICY: June 23, 2006