POLICY NUMBER 2015-07
June 9, 2015

POLICY: CLINICAL RECORD DOCUMENTATION REQUIREMENTS FOR PARTICIPANTS PARTICIPATING IN A CLINICAL TRIAL

PURPOSE:
To delineate federal and institutional compliance requirements that govern clinical trials conducted at UConn Health when they include clinical services, items or procedures that are provided by UConn Health faculty providers or employees. Specifically, this policy relates to Medicare's requirement to document in the patient's clinical record information that describes the clinical trial in which the patient is a participant.

SCOPE:
This policy applies to medical staff appointees, students, faculty and all UConn Health employees who conduct research involving human subjects within the UConn Health system.

POLICY STATEMENT:
All clinical services and procedures have specific requirements under Medicare, Medicaid and other third party payors. If any charges are directed toward the patient or insurance when a patient is participating in a clinical trial, Medicare requires that the following information be documented in the clinical record to clearly identify that the patient is a participant in a clinical trial:

1. Clinical Trial name
2. Sponsor name
3. Sponsor protocol number[1]

Currently Medicare does not require this information to be submitted with the claim, but it must be provided if requested during a Medicare review. This detailed information need only be documented once in the patient's clinical record, however each clinical visit associated with this clinical trial must be clearly identified as such in the clinical record.

Overview:
Accountability for compliance with laws, regulations and applicable UConn Health policies pertaining to the identification and billing of patient research charges is ultimately vested with the principal investigator conducting the research activity or an authorized collaborating investigator who is responsible for overseeing treatment of subjects in the clinical trial. This includes the delineation of Protocol Induced Costs and Routine Clinical Services before the

[1] Medicare Claims Processing Manual, Chapter 32, §·69.3- Medical Records Documentation Requirements

clinical trial receives IRB approval. The complexity of the laws, regulations, and policies require that UConn Health investigators, administrators and staff work collaboratively with staff in the Office of Clinical and Translational Research (OCTR) so that a comprehensive Medicare Coverage Analysis is completed by OCTR staff before the study receives IRB approval. This procedure is done to determine the status of the trial as a "qualifying clinical trial" per the Medicare National Coverage Determination of 2000[2] and that costs are billed appropriately and in compliance with relevant laws, regulations, institutional policies and contractual obligations.
Members of the UConn Health research community are individually responsible for understanding and adhering to UConn Health research billing policies and procedures, participating in required training, fulfilling recordkeeping requirements, reporting compliance concerns, seeking clarification when questions arise and responding in a timely manner to requests for information associated with internal audits or investigations.

The Principal Investigator or an authorized collaborating investigator who is responsible for overseeing treatment of subjects in the clinical trial has additional responsibilities including appropriate documentation to support the medical necessity of the service as well as documentation to support the service being provided. If the patient is a participant in a clinical trial, Medicare requires the information described above in the policy statement (clinical trial name, sponsor name and sponsor protocol number) to be recorded.

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.[3]

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] National Coverage Determination (NCD) for Routine Costs in a Clinical Trial (310.1);CMS
[3] National Institutes of Health (NIH), panel on Clinical Research 1995

Principal Investigator (PI): The researcher with overall responsibility for the direction of a research project, grant or contract.

Authorized Collaborating Investigator: A clinical professional, authorized to document in the medical record per UConn Health administrative policy 12-014, who is overseeing the treatment of subjects in the clinical trial. http://nursing.uchc.edu/hosp_admin_manual/docs/12-014.pdf

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.

Jeffrey Seemann (Signed) 6/19/15

Jeffrey Seemann **Date**
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Andrew Agwunobi (Signed) 6/23/15

Andrew Agwunobi, M.D., M.B.A. **Date**
Interim Executive Vice President for Health Affairs

New Policy: 6/9/15