UCONN HEALTH

POLICY NUMBER 2017-01
February 14, 2017

POLICY: EDUCATIONAL REQUIREMENTS FOR CLINICAL TRIAL BILLING COMPLIANCE (CTBC)

PURPOSE: The purpose of this policy is to identify educational requirements for research personnel who conduct clinical trials which generate research and/or insurance charges, are involved in the designation of routine clinical services (RC) versus protocol induced costs (PIC), are responsible for payment of research charges, and for all staff in the Office of Clinical and Translational Research (OCTR).

Background and Significance: The billing of RC and PIC professional and technical services done at UConn Health must be uniform and compliant with all internal policies as well as all applicable state and federal laws and regulations including, but not limited to, Medicare and Medicaid and in accordance with contractual obligations to third party payers.[1]

It is the policy of UConn Health that individuals directly involved in the designation of RC and PIC (i.e. investigators, coordinators, administrators, JDH and UMG billing staff) or the administration of research billing compliance (i.e. OCTR staff) complete training in Clinical Trial Billing Compliance (CTBC).

The training requirement will be satisfied through completion of an on-line training tutorial approved by the Associate Vice President for Research Integrity and Regulatory Affairs (AVPRR). The on-line modules provided through the Collaborative IRB Training Initiative (CITI) for CTBC will be used at UConn Health.

Scope:
This policy applies to all UConn Health employees, including students who conduct clinical trials which generate research and/or insurance charges for medical, behavioral, social science, outcomes and health services research. It also includes dental staff who conduct clinical trials that generate JDH and/or UMG medical charges, employees who are involved in the designation and/or payment of RC versus PIC charges, and OCTR staff. CITI training for CTBC must be renewed every three years.

[1] Medicare Coverage Policy regarding Clinical Trials, Final National Coverage Decision (NCD)
https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/clinicaltrialpolicies/

If an individual would like to satisfy CTBC training through some other means, that person must obtain approval from the AVPRR. The individual must provide the AVPRR with an overview of the content of the proposed substitution.

If an investigator is external to UConn Health, s/he must submit proof of having completed CTBC training. A letter or certificate of completion from the respective institution may suffice. However, the OCTR reserves the right to require the investigator to complete CTBC training at UConn Health

Procedural Steps:
CITI: Individuals log into the CITI web site to complete CTBC training modules based on their primary research functions. Upon receipt of the completion report from CITI, designated OCTR staff will enter the course completion information into the database.

Responsibilities:
The designated OCTR staff will verify that all investigator and applicable research/ administrative staff have completed the required training by checking the names on a Pre-Packet Budget Workbook (BWB) submission against the database. Verification will be study specific and done for all new clinical trials that require a BWB. To be considered valid and current, the CTBC training must be renewed every three years.

If an individual has not completed CTBC training, OCTR staff will notify the PI and the individual by e-mail.

1. The PI may remove the individual from the study and replace him/her with an employee who has completed the training or
2. If the individual is to remain on the study, the budget initiation and the development of a Banner account will not occur until the requirement has been satisfied.

DEFINITIONS:

Clinical Research:

1) 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. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2) Epidemiological and behavioral studies.
3) Outcomes research and health services research

Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition. [2]

[2] NIH glossary
https://grants.nih.gov/grants/glossary.htm

Clinical Trial: A research study[3] in which one or more human subjects[4] are prospectively assigned[5] to one or more interventions[6] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[7]
3,4,5,6,7

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

Investigator: A medical/dental 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.

Administrative Manager: The person at UConn Health who manages the payment of PIC charges with input from the Study Coordinator.

Jeffrey Seemann (Signed) 3/6/17

Jeffrey Seemann, PhD **Date**
Vice President for Research

Andrew Agwunobi (Signed) 3/9/17

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

New Policy: 2/14/17

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[3] See Common Rule definition of "research" at 45 CFR 46.102(d).
[4] See Common Rule definition of "human subject" at 45 CFR 46.102(f).
[5] The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
[6] An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
[7] A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. *Revised*
https://grants.nih.gov/grants/glossary.htm#ClinicalTrial