University of Connecticut Health Center
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Educational Requirements Relating to Research Financial Compliance	
Relates to Policy:	
SOP#: 1300-17	Version 1.0
Prepared by: Judi Kulko	Original date: December 2, 2017
Approved by: Judith Kulko	Date approved: May 3, 2017

Purpose and Applicability: The purpose of this document 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.[i]

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.

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:

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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.

Revision date:	Revised by:
Reason for revision:	
Date revised version sent to archives & current revision version # advanced:	

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