Purpose and Applicability: To ensure identification and generation of accurate, consistent and appropriate billing of patient research-related charges. A Medicare Coverage Analysis will be conducted for each study before submission to the Institutional Review Board (IRB) for approval and all protocol Induced Costs (PIC) and Routine Care Costs (RC) on a per patient basis will be identified and delineated.

Background and Significance:
See SOP 1200-17

Scope: All such charges will be identified in the Billing Protocol (PRL) record within Epic for each study. Billing protocols are created and maintained by the HealthONE Research Team. The budget workbook produced by the Office of Clinical and Translational Research (OCTR) will be utilized in the creation of billing protocol and subsequent changes to the billing protocol.

Responsibilities: Billing protocols will auto-adjudicate research-related PIC and RC charges within the Epic EMR. All charges will be held for review once a patient is consented in a clinical trial – whether research-related or not. There may be charges that are research related that are not in the billing protocol – for example, charges related to an injury that is due to participation in the clinical trial. All such charges qualify for a two-tier UConn Health review. Due to the generation of charges on a constant basis within Epic, both reviews must be performed on a routine and continuing basis. First-tier review will be conducted on a daily basis (M-F) by study coordinators. Study coordinators will review all charges for their patients’ visits and determine whether the charge is assigned to the correct payor. If the payor is incorrect, the study coordinator will make corrections as needed (e.g., mark an RC charge as a PIC charge or vice versa and/or indicate that a charge is NOT related to the given study). The study coordinator will then mark the charges as reviewed. The charges will then become available to OCTR staff to perform second-tier review. OCTR staff will perform second-tier review on a daily basis (M-F). OCTR staff will review all charges and will either 1) make any corrections to such charges as needed (e.g., change the payor, modify a CPT or charge code, or correct the amount), then marked the account(s) (both hospital and professional accounts) as reviewed. Once second-tier review is complete within Epic, charges will continue to be processed by the system in order to generate research statements or patient claims. Any change that OCTR makes to a PIC or RC charge will qualify for study coordinator re-review.
If a disagreement exists between the study coordinator/PI and the Office of Clinical and Translational Research staff concerning the delineation of services as PIC or RC within a clinical trial, the Associate Vice President for Research will meet with the PI to resolve the disagreement. If the disagreement is not resolved, the Associate VP will 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 VP 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 VP.