

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Monitoring / Auditing of Research Billing Compliance	
Relates to Policy/Procedures: 2006-12	
SOP#: 801-09	Version 6.0
Prepared by: Judie Fine	Original date: 7/30/09
Approved by: Judi Kulko	Date approved: 8/24/16

Purpose and Applicability: The purpose of this document is to outline the monitoring / auditing process of the Program.

Background and Significance: Please see SOP 800-09

Scope: These procedures apply to all research-related activities from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within UConn Health.

Responsibilities: The OCTR Executive Administrator, with appropriate staff, is responsible for implementing and maintaining this Research Financial Compliance Monitoring Program.

Procedural Steps:

Selection of Studies for Audit:

Most studies chosen for a compliance / billing audit will be clinical trials identified through a random process. There will be a focus on:

- Studies that combine both protocol induced costs (PIC) and routine clinical services (RC)
- Investigator initiated studies

Types of Research Financial Compliance Audits:

A. Random Audit for Financial Compliance

Scheduled audit: This type of review is considered a full audit. Focus of review includes:

- budget determination
- delineation of PIC and RC
- adherence to the Medicare National Coverage Decision (NCD)
- adherence to UConn Health research financial policies and state laws and regulations
- appropriate approval from Medicaid and other third party payers for payment of RC associated with a clinical trial.
- review may also include
 - i. review of contract
 - ii. review of PIC paid by sponsor

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- iii. review of RC paid by third party payer or participant
- iv. review of all patient charges / billing
- v. review of any charges / billing for adverse events
- vi. review of charges billed to the study Banner account #
- vii. changes in budget
- viii. changes in contract

Unscheduled audit: This type of audit is done to assess one or two elements of the full audit, such as

- budget delineation, or
- patient charges

B. For Cause Audit for Financial Compliance

Performed when concerns regarding research financial compliance are brought to the attention of the OCTR, the Human Subjects Protection Office, Institutional Review Board or Research Compliance.

Elements of an Audit

A. Roles and Responsibilities

The following items will be reviewed to understand the roles and responsibilities of the research team as they relate to financial compliance and clinical research:

- budget workbook
- delineation of PIC and RC
- adherence to UConn Health policies
 - i. opening a clinical trial
 - ii. identifying research patients
 - iii. establishing a unique research billing number
- verification of Continuous Monitoring Process (CMP) by study staff

B. Compliance / Case Review

- Assessment of compliance with UConn Health policies
 - i. research patient billing policies and procedures
 - ii. identification of inpatient and outpatients services
 - iii. designation of PIC and RC
 - iv. opening a clinical trial
 - v. attainment of Billing Employer Account Number (BEAN)

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- vi. identification of research subject by obtaining an individual Case Number for each research subject
- vii. correct billing procedure for charges
- viii. identification of errors and corrective plan of action
- review may also include
 - i. documentation of research intervention
 - ii. subject accrual
 - iii. review of research records
 - iv. review of clinic / medical records
- Assessment of compliance with State of Connecticut regulations and laws relevant to billing of patients on clinical trials
- Assessment of compliance with Federal regulations and laws relevant to billing of patients on clinical trials.

C. Informed Consent

- Confirm consistency between contract, protocol and approved Informed Consent as it relates to financial compliance
- Confirm consistency between Informed Consent and actual patient charges as it relates to financial compliance
- Review may also include
 - i. dates of approval and start of research
 - ii. changes in protocol

Notification and Timing of Audits

A. Notification:

- Email notification of pending audit is sent from the OCTR Administrative Fiscal Assistant (see SOP 802-09 for letter template and enclosure). It is the responsibility of staff in OCTR to schedule the visit after notice has been sent.

B. Timing:

- Studies for random audits are selected quarterly, and scheduled one per month
- Random audits are scheduled two to four weeks in advance; however unscheduled "mini" audits may be performed within 5 days.
- For Cause Audits may be performed without prior notice

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Report of and Follow-up on Audit Findings

A. Preliminary Report of Audit Findings

- Based on the Research Financial Compliance Audit, a "Preliminary Audit Results" letter is sent to the Principal Investigator , Study Administrator and Study Coordinator within 30 days of the audit
- The PI is given approximately 30 days (with specific response date stated in the letter) to review it for accuracy and respond with answers to any questions and/or explanations for specific situations noted.
- When all questions have been answered, and valid explanations provided, the Preliminary Audit Results letter will be revised to reflect PI/study staff responses
- If no response is received by the response date, the preliminary results will be considered "final".

B. Violations

- Major billing financial violations, or substantive systematic deficiencies are reported immediately to the Associate Dean of Clinical Research Planning and Administration.

Final Report of Audit Findings

A. A "Final Audit Results" letter is provided to the Principal Investigator, Study Administrator and Study Coordinator with copies to the Associate Dean of Clinical Research Planning and Administration, Associate Vice President Sponsored Programs and Services, and Director of Sponsored Programs and Services.

- The For Cause Audit Final Results letter is provided to the PI's Department Chair/or Center Director.
- If major violations or substantive systematic deficiencies are identified, the final audit letter is also sent to the PI's Department Chair/or Center Director.

The letter includes:

- comments on audit procedure and the findings
- description of deficiencies or violations
- recommendations for corrective action plan, including correcting billing errors

B. If there are outstanding unresolved issues, the Investigator is given 21 days to respond with a corrective action plan.

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C. If Investigator does not respond with a corrective action plan to remedy the outstanding issues and prevent the issues from occurring in the future within 60 days of the final audit letter, the Executive Administrator of the OCTR will notify the Associate Dean of Clinical Research Planning and Administration, Associate Vice President Sponsored Programs and Services, and Director of Sponsored Programs and Services. Further actions will be decided by this group and any other people deemed necessary to resolve the issues.

D. When all corrective actions have been completed and no outstanding items remain, a letter of acknowledgement is sent to the PI and the audit is officially closed.

Revision date: 8/24/16; 10/29/15; 4/29/15; 6/19/14; 2/28/14 Revised by: D. Clavette; J. Kulko
Reason for revision: 6.0 Name Change 5.0 Addition of consequences of not responding to audit results 4.0 Change time limitations to send out audit report and respond to audit report 3.0 Change audit report distribution list 2.0 To change FRS # to Banner #
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