

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Procedural Steps and Responsibilities in the Financial Compliance Audit Process	
Relates to Policy/Procedure: 2006-12	
SOP#: 803-11	Version 5.0
Prepared by: Judie Fine	Original date: 4/3/11
Approved by: Judi Kulko	Date approved: 8/24/15

Purpose and Applicability: The purpose of this document is to outline the procedural steps and individual responsibilities in the financial compliance audit process.

Background and Significance: Please see SOP 800-09 and SOP 801-09

Scope: These procedures apply to all financial compliance clinical trial audits undertaken by the Office of Clinical & Translational Research.

Responsibilities: OCTR Administrative Fiscal Assistant, under the supervision of OCTR Executive Administrator, is responsible for the entire clinical trial audit process, including but not limited to random selection of trials for audit, timing, scheduling, maintenance of the Audit Calendar on the OCTR Shared Drive, pre-audit activities, audit day preparation, audit day and audit day follow-up as described in SOP 801-09, as well as audit close-out procedures, documentation and electronic/hard copy filing.

Procedural Steps:

Documents and templates *italicized* below may be found in SOP 802-09, Forms & Templates – Research Financial Compliance Monitoring Program, at the Appendix letter indicated in parentheses.

A. Selection and tracking of trials for audit: In the first week of every quarter, three clinical trials are randomly selected for audit, i.e., one trial to be audited per month. Upon identification of upcoming audits, and using the *Audit Calendar Tickler* (xls) on the OCTR Shared Drive (Appendix D) **enter into appropriate columns:**

- audit month/year
- names of PI and study coordinator
- IRB #
- fragment of study name for reference, and sponsor
- date to send email notification memo to PI (first week of month preceding audit)
- date by which audit is to be scheduled (approximately two weeks following email)
- date by which audit is to be completed (last business day of the audit month)

Upon scheduling an audit, **enter:**

- date scheduled for audit and completion of *Financial Compliance Audit Form* (Appendix B)
- date draft results letter is due to the Executive Administrator (usually two weeks following the actual audit)

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The *Audit Calendar Tickler* should be checked frequently for task due dates.

B. First week of month preceding audit month (e.g., first week in Nov. for Dec. audit):

- email *Memorandum of notification of pending audit* (Appendix A) with accompanying “audit activities” enclosure to PI, covering study coordinator
- print out *Research Financial Compliance Audit Checklist* (Appendix J) for specific audit, fill in PI name and IRB#, and prospectively check off each item as completed

C. Two weeks prior to each monthly audit:

- obtain IRB-approved informed consent form (ICF) from study coordinator
- print Patient Services Calendar from the final Budget Workbook for each auditor
- schedule audit-preparation meeting with Executive Director to:
 - i. review Budget Workbook for completeness
 - ii. review Medicare qualifying form
 - iii. review IDE qualifying form (if applicable)
- email *Research Financial Compliance Audit Requirements* form (Appendix I) to study coordinator to request:
 - i. recruiting status of study
 - ii. list of enrolled and screen failed patients with name, T#, case #, study ID#, date ICF signed and date randomized , if applicable
 - iii. building/room # reserved for scheduled date & time of audit
 - iv. research charts be available, including inpatient charts for inpatient studies
 - v. clinic/medical records be available for each patient, including screen failures
- Using final version of study protocol, IRB-approved ICF, preliminary Budget Workbook packet, and Budget Workbook Patient Calendar, develop study-specific *Audit Tool with Problem Sheet* form (Appendix C), addressing on the form any questions and/or inconsistencies uncovered in the above review, as appropriate.
- Decide if all patients will be audited, or a randomly-selected percentage of patients
- Prepare list of selected patients; include patient name, T# and case #; email to study coordinator or RN; reiterate **in email that research charts, as well as patient medical records, must be available day of audit to provide source documentation.**

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- after patient selection and *Audit Tool* completion, prepare an *Audit Tool with Problem Sheet* form for each case selected

D. Day of audit:

- Take all documents used in above review and preparation
- Following patient chart reviews, and prior to leaving audit area, review and complete on the *Financial Compliance Audit Form* (Appendix B) all appropriate items (study documents, policies, etc.).

E. Reconciliation of audit findings

- Using the UConn Health IDX systems ADT for John Dempsey Hospital (JDH) charges, and BAR for UConn Medical Group (UMG) charges, and for every patient audited, review each Routine Clinical Service (RC) and Protocol Induced Cost (PIC).
- Whether charged correctly, or incorrectly, print documentation of **every** charge and attach to the *Audit Tool Problem Sheet*.
- Using *Problem Sheet*, list all charging errors, and/or questions about possible charging errors for inclusion in the *Preliminary Results of Audit Letter* (Appendix E).

F. Within 1 month following audit:

- If major billing financial violations or substantive deficiencies are found, follow procedures on page 4 of SOP 801-09 under “Violations”
- If there are no major violations or deficiencies, **undated** draft of *Preliminary Results of Audit Letter* is to be sent to Executive Administrator for review and approval; letter should state PI has 30 days from **date letter is sent** to review for accuracy and respond if there are comments and/or questions.
- After approval of draft *Preliminary Results Letter*, **date letter, add PI specific response date**, email to PI, study coordinator and/or department administrator, post *Letter* to Shared Drive Audit folder and both dates to *Audit Calendar Tickler* xls spread sheet on Shared Drive

G. PI reviews, comments and responds to queries. If there are changes identified by the PI, that should be made before the final report is distributed, the agreed upon changes are made and the final audit report is distributed to the people identified on the distribution list. (5 of SOP 801-09 under Final Report of Audit Findings)

H. Finalizing the audit process

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- PI has 21 days to respond to the final audit report
 - Response must include plan to rectify any identify problems
 - Plan to prevent problems in the future
- If the PI has not responded by date specified in the final audit report, follow procedures on page 4 of SOP 801-09, under “Final Report of Audit Findings”.

I. If there are charges to be reversed:

- OCTR sends JDH and/or UMG and/or Dental incorrect charges to:
 - UMG to Patient Service Representative (copying University Physician Accounts Director), and
 - JDH to Patient Services Assistant designee (copying University Director of Patient Services) requesting that incorrect charges be corrected and re-billed appropriately
 - Dental to the Supervisor of Patient Service accounts (Axiom)
- request that notification of reversal be made to OCTR by two weeks from date of memo; add response date to *Audit Calendar Tickler* (xls) on OCTR Shared Drive
- if notification of reversals is not received by two week mark, send another email stating confirmation has not been received and closing of audit file is dependent upon charge corrections; request date by which reversals will be made
- when promised date is received, add to *Audit Calendar Tickler* on Shared Drive and follow-up appropriately until notification of reversal has been received
- after notification of reversals has been received, send email to PI informing her/him that audit is officially closed
- post copy of PI email to Shared Drive in Audit folder and add paper copy to audit hard copy file

J. Electronic and hard copy filing of audit:

- using *Check List for Contents of Paper Audit File & Shared Drive* (Appendix K), create a hard copy file labeled with audit name, PI and IRB#, and file documents from oldest on bottom to newest on top, as they appear on the *Check List*.
- staple the completed *Check List* to left, inside front cover of the file; note that the “n=___” should be filled in
- create an “audit folder” on the Shared Drive under “Audits”, and name folder using PI last name

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- post all final documents to the Shared Drive Audit **except** for the patient-specific Audit Tool(s) with Problem Sheet and IDX print-outs
- **Only the final document** of each type should be posted to the audit folder. If a draft document was temporarily placed on the Shared Drive, it should be deleted at the time the final document is created and posted
- When completed and **signed**, scan *Financial Compliance Audit Form* (Appendix B) and post to the Shared Drive audit folder

Revision date: 8/24/16; 10/29/15; 2/28/14; 8/11/11 Revised by: D. Clavette, J. Kulko
Reason for revision: 5.0 Name changes 4.0 Change time limitations to send out audit report and respond to audit report 3.0 To update personnel involved to titles rather than names 2.0 To update personnel involved in section G
Date revised version sent to archives & current revision version # advanced: 8/24/16