UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Forms & Templates – Research Financial Compliance Monitoring Program	
Relates to Policy/Procedures: 2006-12	
SOP#: 802-09	Version 8.0
Prepared by: D, Clavette	Original date: 7/30/09
Approved by: P. Hudobenko	Date approved: 6/30/18

Purpose and Applicability: Documents and templates in this section are used in the Program

Background and Significance: Please see SOP 800-09

Scope: These forms and templates facilitate interaction between the OCTR, the PIs and/or PI designee; standardize the auditing process as well as the office procedures related to documenting audits.

Responsibilities: The OCTR Executive Administrator and appropriate staff are responsible for the design, development and appropriate use of these forms and templates.

Procedural Steps:

NOTE: The header in this SOP is applicable only to the leading two pages listing forms, and not to individual documents, which are routinely edited to reflect changes in usage and/or procedures. Changes to individual documents are noted on each document page.

Form labeled A: Memorandum template with notification of pending audit, with enclosure used (2 pages)
Form labeled B: Financial Compliance Audit Form (internal form - 2 pages)
From labeled C: Basic Audit Tool template, modified for each audit as appropriate to the study design and the Budget Workbook Patient Calendar; “problem sheet" to be attached to each patient's Audit Tool
Form labeled D: Research Financial Compliance Audit Schedule – Column headings for Excel spread sheet on OCTR Shared Drive
Form labeled E: Letter template to PI with preliminary audit findings - with **"Preliminary"** watermark (3 pgs)
Form labeled F: Letter template to PI with final audit findings (with **"Final"** Watermark
Form labeled G: email template with final audit summary to Associate Dean Clinical for Research Planning and Administration, Associate Vice President Sponsored Programs and Services
and Director of Sponsored Programs and Services
Form labeled H: email template to PI with appreciation and acknowledgement of audit closure

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Form labeled I: Research Financial Compliance Audit Requirements – emailed to Study Coordinator after Notification of Audit
Form labeled J: Research Financial Compliance Audit Checklist – specific to each audited study
Form labeled K: Check list for contents of paper audit file & shared drive – to be taped to inside cover of paper file
Form labeled L: UMG Research Study Billing Reversals
Form labeled M: JDH Research Study Billing Reversals
Form labeled N: Research Study Missing Charges

Revision date: 8/11/11;2/28/14; 8/24/16; 6/30/18	Revised by: D. Clavette
Reason for revision: 8.0 Name changes 7.0 Name changes 5.0 To add new forms L. M and N 4.0 To change Forms labeled A, G & I. In order to insert current names.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

Email accompanying the Notice of Audit Memorandum **A**

Dear Dr.

Your study IRB # xx-xxx-x *Study Name* has been identified for a routine research financial compliance audit. OCTR will contact xxx (study coordinator) to schedule a date for the review. The attached memo provides details. The audit should be conducted prior to (date). Please contact me at x8924 with any questions about the memo or audit. Thank you

Office of Clinical & Translational Research

MEMORANDUM

To: XXXX., Principal Investigator

From: Executive Administrator, Office of Clinical and Translational Research

Date: XX/XX/XX

Subject: **Research Financial Compliance Monitoring Program**

Study to be audited: **XXXXXXXX**

The Office of Clinical & Translational Research (OCTR) of the UConn Health is committed to the improvement of the quality, efficiency, integrity and compliance in our research environment and activities. In pursuit of this commitment, the OCTR supports a **Research Financial Compliance Monitoring Program** to assess financial compliance with federal, state and institutional policies pursuant to billing activities and clinical research.

The objective of the Financial Compliance component of the Quality Assurance (QA) Program is to ensure that subject billing adheres to the regulations set forth in the Medicare National Coverage Decision for Institutional Review Board (IRB) approved clinical protocols.

IRB XXXX; XXXXXXXXXXXX

has been selected for the purpose of a financial compliance audit. The audit staff will phone your office within the next week to arrange for a mutually agreeable time to conduct the audit. The target date for the audit is XX/XX/XX.

A pre-audit interview will be conducted with you and the study coordinator to discuss this research study and related financial compliance issues. This interview will involve approximately 10 minutes of your time. Your presence during the course of the audit is not necessary. Availability of a conference room or quiet area for the day for the audit staff to review patient records and other associated documents will be necessary. Documents pertaining to your clinical research will be held strictly confidential.

Please contact, (insert name); at 8924 if you have any questions or concerns.
Enclosure (1)

Enclosure accompanying Audit Memorandum

FINANCIAL COMPLIANCE AUDIT ACTIVITIES MAY INCLUDE:

IRB Process

Dates of approval and start of research
Changes in protocol

Budget and Billing process

Review of contract
Review of approved budget
Review of protocol induced costs paid by the sponsor
Review of routine care costs paid by third party payer/participant
Review of all patient charges/billing
Review of any charges/billing for adverse events
Review of billing process within the department (adherence to UCHC SOPs)
Review of charges billed to the study FRS account #
Changes in budget
Changes in contract

Records regarding Subjects

Documentation of research intervention
Subject accrual

Documentation

Review of research records
Review of clinic/medical records

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off contact name in order to have current person to insert name.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

B

Internal form

FINANCIAL COMPLIANCE AUDIT FORM

Principal Investigator:
_____

Study Name:
_____

IRB #:_____ **BANNER account #:_____**

	Documents	Yes	No	Comments
Source Documentation	Sponsor identified			
	Budget provided by sponsor			
	Contract provided.			
	Consent identifies services that are PIC and RC			
	Compensation for patient injury is the same in contract and consent			
	Consent, Protocol, Budget all concur regarding patient services and payment for patient services			
	IND #			
	IDE #			
	Appropriate approval from MAC for IDE studies			
Policies	Is this a qualifying study under CMS guidelines			
	For IDE studies and carotid stent registries, appropriate notification has been submitted to MAC for payment preapproval			
Results	Individual PIC patient charges were checked and compared to source documentation for services provided and required services per protocol			
	Hospital charges were reviewed in EPIC			
	UMG charges were reviewed in EPIC			

	Representative sample of charts were reviewed			
	Were errors found in billing (describe in attachment)			
	Is this a departmental problem			
	Is it a system problem			
	All charges reversed; AUDIT CLOSED			Date
	SIGNATURE:			**SIGNATURE:**
	Executive Administrator, OCTR			**Financial Compliance Auditor**

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off signature name in order to have current person to insert name.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

Example of template for Basic "Audit Tool"
(Tool is unique to each study)

C
Internal Form

Medicare Qualifying Form reviewed: XX yes (not Medicare eligible) □ no □ NA **IDA Qualifying Form reviewed:** □ yes □ no XX NA

Correct discounts reviewed and taken: □ yes □ no □ NA

Patient Name: _____ TO# _____
Date ICF signed: _____ Date randomized: _____ **Note:** No routine care indicated in Budget Workbook

Additional space for notes on page 4

CPT	description	UMG/JDH	date	PIC charged to study?	PIC erroneously charged to insurance?	Other billing errors	Comments
99204 99xxx	Comprehensive/moderate OP visit-new –screening visit	UMG					
94010	Spirometry	JDH					
99195 (from packet)	Screening visit blood draw *	JDH					budget workbook = T & E only * protocol, packet and BW indicate 2 blood draws; ICF indicates 3 blood draws
94240	Screening functional residual capacity/volume	JDH					
94720	Screening carbon monoxide diffusing capacity	UMG					
94720	Screening co diffusing capacity	JDH					
99xxx	Baseline OP visit	UMG					
93320	Baseline visit Doppler ECHO	UMG					
93320	Baseline visit cardiac Doppler	JDH					
93000 (BW) 93040 (from	Baseline visit ECG	UMG					

packet)							
93501	Baseline visit right heart catheterization	UMG					

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off Case # - Case numbers no longer needed.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

Example of problem Sheet to be attached to each patient's Audit Tool

PROBLEM SHEET: IRB# (insert Number), (insert protocol), (insert PI)

Pt last name_____

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: To take off Case # - Case numbers no longer needed.	
Date revised version sent to archives & current revision version # advanced:	

Research Financial Compliance Audit Schedule **D**

Column headings on Excel spread sheet on OCTR Shared Drive

audit month FY 2011	send email memo re audit	OCTR set up audit date by	audit to be completed by - date	date of audit & completion of Fin Comp Audit Form	draft letter due to JK1	preliminary letter sent to PI	date PI response due	final letter sent to PI

date PI response due	date letter sent to Res Adm & closed	PI & coordinator	IRB#	study name fragment & sponsor

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

E

Letter template to PI with preliminary audit findings – with **"Preliminary"** watermark (3 pgs)

Date

Dr. XXX XXXXX
Department
MC ####
University of Connecticut Health Center

Regarding: IRB # YY-###-1 Name of Study

I am writing to provide you with the preliminary results of the MM/DD/YY research financial compliance audit on the above mentioned study. The purpose of such audits is to provide a systematic internal process that will increase compliance with Federal, State and institutional regulations and policies. The research financial compliance monitor conducted the audit with your study coordinator, YYY YYYYYY.

Study Summary:
The purpose of this study is to demonstrate that …

Patient Injury Language:
The final contract and patient consent were reviewed to check for consistency in patient injury language in both documents and XX issues were identified.

Notification of Medicare Administrative Contractor (MAC):
Per Center for Medicare & Medicaid (CMS) policy, appropriate verification was obtained by study coordinator from our MAC to support Medicare patient participation and Medicare payment for patient participation in the XXX trial…

Budget Workbook:
Per UConn Health policy, a budget workbook was completed for this study prior to IRB approval. This workbook was used as a template to review Protocol Induced Costs (PIC) and Routine Clinical Services (RC).

Patient Charges:
Actual dates of patient PIC and RC services were identified in the patient research record. If discrepancies in dates of service were identified, the patient Lifetime Clinical Record (LCR) was reviewed. IDX, the UConn Health billing program, was then used to verify if PICs and RCs were billed correctly to research and insurance respectively.

Findings:
A total of ## patients signed consent to participate in this clinical trial. Patient xxxxx was a screen failure; patient yyyyy did not participate in the study and patient…

Routine Clinical Services

- All routine clinical services identified in the budget workbook were billed correctly to the patients' insurance for JDH charges.
- Patient.zzzzz had all UMG charges for xxxxx procedure done on MM/DD/YY erroneously charged to the research study.

- Patient qqqqq had all UMG charges for xxxxx procedure done on MM/DD/YY erroneously charged to the research study.

Protocol Induced Costs
Protocol induced costs identified in the budget workbook and designated as being paid by the sponsor included… The findings are as follows:

- The xxxxx examination required by the study was done per protocol… by xxx xxxx, for each patient. No specific charges were found for this service. This was designated as a protocol induced cost for which the sponsor paid. Therefore, a visit should be charged to the study for each of these examinations, or her time should be charged to the research account as T&E.

- XXX, (which include JDH charges to do the XXX and UMG charges to read the XXX), for patient zzzzz was charged correctly to the research through use of the case number. Errors were found in the remaining five patients and are delineated below:

1. Patient ccccc:

2. Patient rrrrr:

3. Patient ooooo:

4. Patient eeeee:

UMG has been notified of the error for patient ccccc and patient kkkkk and the routine clinical services related to the xxx procedure have been charged correctly to each patient's insurance to avoid non-payment due to time limitations.

The remainder of the UMG charges billed erroneously to insurance and the T&E for the xxxxx exams will be charged to the research as soon as we receive confirmation from you that you have reviewed these findings and have no further comments.

We would like to thank your staff, specifically, YYY YYYYYY, for her participation in this monitoring process. Please respond to these preliminary findings within 15 days (by MM/DD/YY) with any comments or questions. If there are no changes to this report, the charges in question will be corrected and this report will be distributed to Research Administration.

Regards,

Executive Administrator
Office of Clinical & Translational Research

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off name in order to have current person name inserted.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

F

Letter template to PI with final audit findings (with **"Final"** watermark

Date

Dr. xxxx
Department
MC ####
University of Connecticut Health Center

Regarding: **IRB # YY-####** *name of study*

This is the final report of the mm/dd/yyyy research financial compliance audit on the above mentioned study. The purpose of such audits is to provide a systematic internal process that will increase compliance with Federal, State and institutional regulations and policies. The research financial compliance monitor conducted the audit with your study coordinator, xxx yyyyy.

Study Summary:
The purpose of this study is to demonstrate …

Patient Injury Language:
The final contract and patient consent were reviewed to check for consistency in patient injury language in both documents and no issues were identified.

Notification of Medicare Administrative Contractor (MAC):
Per Center for Medicare & Medicaid (CMS) policy, appropriate verification was obtained by study coordinator from our MAC to support Medicare patient participation and Medicare payment for patient participation in the xxxxx which is an Investigational Device Exemption (IDE) study.

Budget Workbook:
Per UConn Health policy, a budget workbook was completed for this study prior to IRB approval. This workbook was used as a template to review Protocol Induced Costs (PIC) and Routine Clinical Services (RC).

Patient Charges:
Actual dates of patient PIC and RC services were identified in the patient research record. If discrepancies in dates of service were identified, the patient Lifetime Clinical Record (LCR) was reviewed. IDX, the UCHC billing program, was then used to verify if PICs and RCs were billed correctly to research and insurance respectively.

Findings:

A total of xx patients signed consent to participate in this clinical trial. Patient T00 ##### was a screen failure; patient T0 #### did not participate in the study and patient T00 #### participated in the trial twice and was counted as two separate subjects.

Routine Clinical Services

- All routine clinical services identified in the budget workbook were billed correctly to the patients' insurance for JDH charges.
- Patient.T00 #### had all UMG charges for xxxx procedure done on mm/dd/yy erroneously charged to the research study.
- Patient T0 #### had all UMG charges for xxxx procedure done on mm/dd/yy erroneously charged to the research study.

Protocol Induced Costs

Protocol induced costs identified in the budget workbook and designated as being paid by the sponsor included one pre-discharge ECG and three neurologic examinations per eligible patient. The findings are as follows:

- The xxx examination required by the study was done per protocol by xxx yyy, for each patient. No specific charges were found for this service. This was designated as a protocol induced cost for which the sponsor paid. Therefore, a visit should be charged to the study for each of these examinations, or her time should be charged to the research account as T&E.

- xxxs, (which include JDH charges to do the xxx and UMG charges to read the xxx), for patient T00 #### and patient T00 #### were charged correctly to the research through use of the case number. Errors were found in the remaining seven patients and are delineated below:

5. Patient T00 ####
6. Patient T00 ####
7. Patient T00 ###
8. Patient T00 ###
9. Patient T00 ####
10. Patient T00 #####
11. Patient T0 ####

UMG has been notified of the error for patient T00 #### and patient T0 #### and the routine clinical services related to the xxx procedure have been charged correctly to each patient's insurance to avoid non-payment due to time limitations.

Please respond to the findings of this audit by mm/dd/yy and outline an action plan to correct the following deficiencies:

- Charging T&E for the xxx examinations done by your Study Coordinator to the study
- Reversing charges and billing research for seven UMG charges for xxxs that were erroneously billed to insurance.

If you have any questions please do not hesitate to contact me at 1395.
Regards,

Executive Administrator
Office of Clinical & Translational Research

CC: P. Albertsen
M. Glasgow
P. Hudobenko

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off name to have current name inserted.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

G

Email template with final audit summary

Email to:

Peter Albertsen, M.D., Associate Dean Clinical Research, Planning, and Coordination
Mike Glasgow, Associate Vice President Sponsored Programs and Services, Paul Hudobenco, Director of Sponsored Programs and Services

From: (Insert Name), Office of Clinical and Translational Research

Date:

Regarding:

IRB YY-####-# *name of study and PI name*

Attached, please find the final report for the research financial compliance audit of the study named above.

(Insert Name)
Administrative and Clinical Research Coordinator
Office of Clinical and Translational Research
UConn Health

(860) 679-(extension)
(Name)@uchc.edu

H

Email template following audit

Date

Dr. xxx yyyy
Department
MC 0000; UConn Health

Regarding: IRB YY-####-

Dear Dr. yyyy,

We appreciate your and your staff's cooperation in conducting this research financial compliance audit. We have received your response to the audit findings and will await a request from bbbb ddddd to meet with her, Department staff, and mmm tttttt to resolve any outstanding issues. Once those issues have been resolved, we will consider this audit closed.

Regards,

Executive Administrator
Office of Clinical & Translational Research

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off name in order to have current name inserted.	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

Research Financial Compliance Audit Requirements form **I**

Sent via email to Study Coordinator

Office of Clinical & Translational Research

Research Financial Compliance Audit Requirements

Date of audit:

Principal Investigator:

IRB #:

Name of study:

Recruiting status (e.g., recruiting, closed to accrual, study closed):

At least ten days prior to the audit, please email the following information to OCTR:

List of enrolled patients, including screen failures, with the following:

1. Patient name
2. TO #
3. Study ID #
4. Date randomized, if applicable

Please reserve a room with space for three people. Room # _____ is reserved.

The day of the audit, the following must be available for review:

Research charts
Clinic/medical records for each patient, including screen failures

Please note: Inpatient studies must have inpatient records available

If you have any questions, please contact (insert name) at x 8924 or (name)@uchc.edu

Revision date: 6/30/18	Revised by: D. Clavette
Reason for revision: Take off Case # - Case numbers no longer needed/	
Date revised version sent to archives & current revision version # advanced: 6/30/18	

Research Financial Compliance Audit Checklist/specific for each study **J**

Internal form

Research Financial Compliance Audit Checklist (addendum to OCTR SOP 802-09)

IRB#: _____
Study name (fragment):
_____
PI: _____
Date of Audit: _____

On a quarterly basis:
□ randomly select trials to be audited, by month
□ using Audit Calendar Tickler (xls) on Shared Drive, enter dates for emails, calls, draft results letter, etc.

First week of month preceding audit month (e.g., first week in November for December audit):
□ email audit memo to PI, covering study coordinator (template in SOP 802-09A) with accompanying "audit activities" enclosure

Two weeks prior to each monthly audit:
□ obtain IRB-approved ICF from study coordinator
□ print Patient Services Calendar from final budget workbook x 3 (for each auditor)
□ review Budget Workbook for completeness
□ review Medicare qualifying form
□ review IDE qualifying form (if applicable)
□ request list of enrolled patients, including screen failures, from study coordinator; **request patient name, TO#, study ID#, date ICF signed, date randomized and study recruiting status**
□ using final version of study protocol, IRB-approved ICF, preliminary Budget Workbook packet, and Budget Workbook patient calendar, develop study-specific Audit Tool form, addressing on the form, any questions and/or inconsistencies uncovered in the review, as appropriate
□ decide if all patients will be audited, or a randomly-selected percentage of patients
□ prepare list of selected patients for study coordinator; include patient name, TO#, and case #; email to study coordinator or RN; include in that email: **NB: research charts as well as patient medical records must be available the day of the audit to provide source documentation**
□ after patient selection and Audit Tool completion, prepare Audit Tool form for each case selected

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 Financial Compliance Audit Form to make sure all items (documents, policies, etc.) have been addressed

□ if major billing financial violations or substantive systematic deficiencies, see page 4 of SOP 801-09

Within two weeks following audit:

□ if no major violations or deficiencies, **undated** draft of preliminary results of audit to be sent to Executive Administrator, Office of Clinical & Translational Research for review and approval; letter should note PI has 15 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 response date, send to PI and post date to Shared Drive

If no problems with PI review are encountered, after PI's response time has elapsed:

□ complete Financial Compliance Summary Form

□ follow procedures on page 4 of SOP 801-09, under "final report of audit findings"

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Reason for revision: Take off Case # - Case number no longer needed; change name to Executive Administrator, OCTR	
Date revised version sent to archives & current revision version # advanced:	

K

Check list for contents of paper audit file & shared drive – to be taped to inside cover of paper file

IRB # xx-xxx-x
Study Name:
PI:

□ **Completed** Research Financial Compliance Audit Checklist

□ copy of letter closing audit

□ copy of Final Results letter to PI, including email

□ original, **completed & signed** Financial Compliance Audit Form

□ copy of PI response to preliminary results letter

□ preliminary results letter to PI, including copy of email

□ Study Specific **Audit Tool**, with **Problem Sheet** and **IDX print-outs** attached, for each audited patient (n=)

□ copy of Budget Workbook patient calendar

□ copy of enrolled patient list

□ currently approved ICF

□ PI notification of audit: email + attachment

□ Appropriate documents in this file have been scanned and posted to the shared drive

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

L
Internal Form

UMG Research Study Billing Reversals

Sponsor: **PI:**
Protocol: **IRB Number:**

Patient Name:
T0 Number:

Invoice #	Date Billed	Procedure	Correction	Charge Code	CPT Code	Completed
						☐
						☐

Completed by: _____

Signature: _____

Date: _____

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M
Internal form

JDH Research Study Billing Reversals

Sponsor: **PI:**
Protocol: **IRB Number:**

Patient Name:
T0 Number:

Visit #	Date Billed	Procedure	Correction	Charge Code	CPT Code	Completed
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐
						☐

Completed by: _____

Signature: _____

Date: _____

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Reason for revision: Take off Case Number – Case number no longer needed.	
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N
Internal form

Research Study Missing Charges

Sponsor: **PI:**
Protocol: **IRB Number:**

Patient Name:
T0 Number:

Date Performed	Procedure	JDH or UMG	CPT Code	Bill to:

Completed by: _____

Signature: _____

Date: _____

Revision date: 6/30/18	Revised by: D. Clavette
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