

# Operations Manual

Document: Final Audit Report (F-402)

## Final Audit Report

### Overview

<b>Institution:</b>	<b>Protocol:</b>
<b>PI:</b>	<b>Research Staff:</b>
<b>Audit Dates:</b>	<b>Auditors:</b>
<b>Study Activation Date:</b>	<b>Date of Report:</b>

TO PRINCIPAL INVESTIGATOR:

CC:

FROM AUDITOR (LHMC Research Quality Assurance Program):

<b>AUDIT CONTENT:</b>	<input type="checkbox"/> Regulatory Audit <input type="checkbox"/> Subject Audit <input type="checkbox"/> Other
<b>TYPE OF AUDIT:</b>	<input type="checkbox"/> Routine Audit <input type="checkbox"/> For Cause Audit <input type="checkbox"/> Other
<b>AUDIT SCHEDULE :</b>	Date(s) of Audit:    --    Exit Interview Date:
<b>PROTOCOL DETAILS:</b>	Current Protocol Version/Date: Disease Category: Target Accrual: Accrual Status as of Audit Date:
<b>STUDY STAFF:</b>	Principal Investigator: Study Coordinator: <input type="checkbox"/> NA Study Nurse: <input type="checkbox"/> NA
<b>IRB:</b>	Initial IRB Approval Date: Current Protocol Approval Date: Continuation Approval Date: <input type="checkbox"/> NA
<b>AUDIT DATA:</b>	<ul style="list-style-type: none"> <li>● Total number of subjects enrolled:</li> <li>● Total number of subjects audited:</li> </ul> List:

### Introduction

This audit was conducted as a [for cause or routine] audit in response to the Research Quality team being alerted to [ ]. The auditor contacted the PI and study staff on [date] for audit notification and request of data.

**EDIT ACCORDINGLY:** The focus of this audit was verification of compliance with regulations, protocol compliance, protection of human subjects and data integrity through a review of IRB documents, signed patient consent forms, patient case files, patient medical records, study records, and the excel dataset. A description of detailed audit findings is documented in this report.

I would like to thank [primary contact] for [[his/her] assistance and cooperation throughout this audit.

Please don't hesitate to contact me with any questions or concerns. I can be reached at (781) 744-xxxx or [email]

Sincerely,  
Auditor's signature  
Auditor's title

## Background

This audit was conducted on a [type of study]. The primary objective of the study is to [primary objective]. Per protocol [summarize what should be done based on if audit is focused based or comprehensive]

## Regulatory Files

### Summary of Findings

**EXAMPLE-EDIT ACCORDINGLY:** A regulatory audit was performed by physical inspection of the paper regulatory files. The regulatory documents were kept in 1 binder, tabbed by section and were generally well organized. Files included protocols, consent forms, IRB correspondence (submission packages and approvals), deviations, source templates, CVs, medical licenses and minimal study correspondence. Overall, the regulatory files for this study were mostly complete and any identified discrepancies requiring corrective action are noted below.

### Detailed Findings

The following noncompliance/deficiencies were identified:

<b>Area of identified noncompliance/ deficiency</b> <i>(DELETE: List in order as they appear in the eReg/ reg file)</i>	<b>Noncompliance/ Deficiency</b> <i>(DELETE: State finding and the related policy)</i>	<b>Corrective Action(s)</b> <i>(DELETE: Discuss how to fix and how to prevent from happening again)</i>

## Patient Files

### Summary of Findings

**EXAMPLE-EDIT ACCORDINGLY:** A subject audit was performed by physical inspection of 22 subject's paper files. Five subjects were then chosen at random and their eligibility was confirmed through medical record review. The paper documents were kept in 2 binders. Each subject's documents were clearly separated by a tab and filed in chronological order by study ID. Subject files included the complete, original, signed consent form, progress note, VAS, Hand Grip Test Form, FRAX, and printed notes from the medical record. Overall, the subject files for this study were mostly complete and any identified discrepancies requiring corrective action are noted below.

### Detailed Findings

The following noncompliance/deficiencies were identified:

Subject Initials/ Visit <i>(DELETE: Describe form, subject identifier)</i>	Noncompliance/ Deficiency <i>(DELETE: Discuss what the finding was and reference the protocol requirement)</i>	Corrective Action(s) <i>(DELETE: Discuss how to fix and how to prevent from happening again)</i>

## Final Assessment

### Overall Assessment

- Exceptional:** Demonstrates superior source documentation, high data quality, strong protocol adherence, and full regulatory compliance.
- Satisfactory:** No major noncompliance identified; overall compliance with all regulatory and drug/device requirements. Minor noncompliance issues may be present, and/or any major issues previously identified were fully addressed and documented prior to the audit, requiring no further action.
- Acceptable- Needs Follow-up:** Multiple minor noncompliance issues identified, or a small number of major noncompliance issues that were not addressed or corrected prior to the audit.
- Needs Follow-up:** Multiple major noncompliance issues and/or multiple non-compliant categories identified; or a single major, flagrant noncompliance; or an excessive number of minor issues, including recurring lesser noncompliance
- Unacceptable:** Multiple major noncompliance issues and/or multiple non-compliant categories identified; a single major flagrant noncompliance; excessive minor issues; or recurring patterns of

lesser noncompliance. Any findings suggestive of scientific misconduct, fraud, intentional data misrepresentation, or disregard for regulatory safeguards must be reported immediately to the Research Compliance Committee.

**CORRECTIVE ACTION PLAN REQUIRED – See attached template**

## Final Assessment and Required Action

FOR CAUSE example- EDIT ACCORDINLY [This audit was conducted in response to the study coordinator's discovery of a number of deviations that were not yet reported. After a thorough review of study data and files, it appears protocol compliance is poor. Although many of the findings are considered to be "lesser" noncompliance or deficiencies when appearing individually, the excessive number of repeated noncompliances, missing consents and major deviations is concerning. Per research SOPs, the PI is required to promptly report all deviations. Lack of prompt reporting, and perhaps the PI's unawareness of these deficiencies, has contributed to continued noncompliance. In addition, there were instances where the dataset did not match the source. Given these findings an assessment of "unacceptable" is warranted and a copy of this report should be promptly submitted to the IRB. Since this report will be submitted to the IRB, submission of individual submissions of each deviation noted in this report is not required.

In addition, a corrective action plan is required and should address the following:

- A plan to prevent additional deviations and noncompliance
- A plan to ensure proper consent documentation and processing
- A plan to consider re-evaluating the need of "protocol defined windows" with the potential for protocol amendment
- A plan to promptly submit any new deviations per Research SOPS
- A plan to track study patients more closely and to ensure 1 year follow up measurements will be obtained when possible
- A plan to ensure the accurate recording of study data

All other corrective actions noted in this report should be addressed within 1 month of this report].

**Upon acceptance of the contents of this Final Audit Report, please sign the Statement of Acceptance below and return it to Research Quality Audit Program, 31 Mall Road by Interoffice Mail or Email: {ADD}**

Thank you and your study team for your cooperation during the performance of this audit, your preparation was greatly appreciated.

Submitted by:

## Statement of Acceptance

I accept this Final Audit Report as documentation of the audit findings and I agree to complete the Corrective Action Plan as described, if applicable.

Signature: \_\_\_\_\_  
Principal Investigator

Date \_\_\_\_\_

## Document Attributes

Research Administration

Final Audit Report (F-402)

<b>Title</b>	Final Audit Report		
<b>Author (s)</b>	Stephanie Scala, MA, CCRP Manager, Research Quality Assurance Program	<b>Date of Origin</b>	January 1, 2019
<b>Dates Reviewed/ Revised</b>		<b>Date Last Modified</b>	
<b>Approved</b>	<b>Signature on File</b> Stephanie Scala, MA, CCRP Manager, Research Quality Assurance Program		