

Operations Manual

Document: Audit Response Form (F-402a)

Audit Response Form

INSTRUCTIONS: Use this form to communicate actions taken in response to a Final Audit Report. Please **complete Sections I-III** unless otherwise directed. Upon completion, **email the signed completed plan to [QA email]**. The Research Quality Assurance Program (RQAP) will review the plan and determine its appropriateness. You will be notified of RQAP's assessment within 1 week of receipt.

Section I: Overview

INSTRUCTION: Select **CAP Type** and enter **Date of Form Completion** where indicated below:

Institution:	Protocol:
PI:	Research Staff:
CAP: <input type="checkbox"/> Initial <input type="checkbox"/> Revised <input type="checkbox"/> Follow up # _____ <input type="checkbox"/> Final – Resolution Date:	Date of Form Completion:

Section II: Corrective Actions Taken

INSTRUCTION: List a corrective action for each item requiring follow up as noted in the Audit Findings Report. Please also include date of completion and provide supporting documents (as applicable) for each action (add table lines as needed). The plan should be **SMART-specific, measurable, attainable, realistic and timely**. Add rows as applicable. **NOTE:** The responses must be TYPED. Handwritten responses will not be accepted.

Area requiring action (<i>List directly from Final Audit Report</i>)	Corrective and/or Preventive Action(s) Taken	Date of Completion	Supporting Documents (list and attach as applicable)
Ex. eReg/ Section 010_Logs/ 01_Site Signature & Delegation	CRC obtained missing signature for Jones and created an NTF stating the late signature entry	3/15/2022	Updated signature & delegation log and NTF attached
1.			
2.			
3.			

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4.			
5.			
6.			
7.			
8.			
9.			
10.			

Section III: Overall Responsibility

INSTRUCTION: Sign and obtain appropriate signatures per below fields.

_____ Audit Response Plan Preparer's Signature	_____ Date of Signature
_____ Print Name	

_____ Investigator's Signature	_____ Date of Review and Approval
_____ Print Name	

Section IV: RQAP Response

NOTE: To be completed by the Lahey Research Quality Assurance Program

RESEARCH QUALITY RESPONSE

Quality Assessment Prior to Implementation:

- Approved by RQAP - no further action required**
- Requires modifications as attached or listed below.**

Comments:

Research Quality Assurance Program Signature

Date of Review and Approval

Print Name

Document Attributes

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