Operations Manual

Document: Internal Audit Tool-Regulatory

Overview

Institution:	**Protocol (LCID):**
PI:	**Research CRC/RN:**
Auditor:	**Audit Dates:**
Study Activation Date:	**IRB of Record:**
Date of Report:	

Areas for Review and Findings

(C) = Compliant (M) = Major noncompliance (L) = Lesser noncompliance

Clinical.ly STATUS				
1.	If the study has a **DR-5** issued, is the study status "Live" in Clinical.ly? • *Per RA eReg Policy and SOP, upon issuance of DR-5, the study should be made "live" in Clinical.ly*	☐ NA	☐ Yes **(C)**	☐ No **(M)**
2.	Is the Clinical.ly "stage" accurate, if applicable?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
		TOTAL:	**C:**	**M:** **L:**
FINDINGS/CAP:				

eReg OVERVIEW				
1.	Are all files **named** according to the naming convention set forth in the RA Policy and SOP, *Research Administration Naming Convention?*	☐ NA	☐ Yes **(C)**	☐ No **(M)**
2.	Are **folders** being used correctly per eReg Policy? • Have any subfolders been added inappropriately? • Have any template subfolders been deleted inappropriately?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
3.	Are **NTFs** used appropriately and in accordance with the eReg Policy	☐ NA	☐ Yes **(C)**	☐ No **(M)**
		TOTAL:	**C:**	**M:** **L:**
FINDINGS/CAP:				

STUDY-SPECIFIC PROCEDURES / STUDY MANUAL			
1.	Is there an **eStudy Manual** (eSM) present?	☐ Yes **(C)**	☐ * No **(M)**
2.	Is it fully completed and current?	☐ Yes **(C)**	☐ No **(L)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

CONTACTS			
1.	Is a current **Contact List** present? Alternatively, are contacts listed using Clinical.ly functionality completed in the "Overview" section?	☐ Yes **(C)**	☐ * No **(M)**
2.	Is it fully completed and current?	☐ Yes **(C)**	☐ No **(L)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

PROTOCOL			
1.	Is a current and valid copy of the **IRB-approved protocol** on file? Version #: IRB approval date:	☐ Yes **(C)**	☐ No **(M)**
2.	Are all previous versions of the protocol on file?	☐ Yes **(C)**	☐ No **(M)**
3.	Have all protocols received IRB approval? RA approval (external IRB)?	☐ Yes **(C)**	☐ No **(M)**
4.	For protocols with a **Protocol Signature Page**, is it complete, signed & dated by the PI?	☐ Yes **(C)**	☐ No **(L)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

INFORMED CONSENT FORMS			
1.	Is a current and valid copy of the **local Informed Consent** Form on file?	☐ Yes **(C)**	☐ * No **(M)**
2.	Are all *previous* versions of the **Sponsor and LHMC** versions of the ICF on file?	☐ Yes **(C)**	☐ No **(M)**
3.	Have all versions been approved by the IRB? RA (external IRB)?	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

INVESTIGATOR BROCHURE

1.	Are all versions of **IB** on file? • If applicable, is the IB signature page signed?	☐ NA	☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(M)** ☐ No **(L)**
2.	If applicable, are package inserts for on file for FDA approved drugs?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
3.	Have all versions of IB and/or package inserts been approved by IRB?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:		**C:**	**M:** **L:**
FINDINGS/CAP:				

CVs & MEDICAL LICENSES; CITIs				
1.	Are current **CVs** (signed & dated within 2 years) on file for the PI and all sub-investigators? • Are all previous versions filed (to represent their participation from IRB Approval throughout duration of study)?		☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(L)** ☐ No **(L)**
2.	Are current **medical licenses** on file for the PI and all sub-investigators? • Are all previous versions filed (to represent their participation from IRB Approval throughout duration of study)?		☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(M)** ☐ No **(L)**
3.	Are current **CITIs** on file for all study staff, if required? • Are all previous versions filed (to represent their participation from IRB Approval throughout duration of study)?		☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(M)** ☐ No **(L)**
	TOTAL:		**C:**	**M:** **L:**
FINDINGS/CAP:				

FORM FDA 1572 / INVESTIGATOR AGREEMENT ☐ **NA (not drug trial)**				
1.	Is a Form **FDA 1572** (for IND studies) or an Investigator Agreement (for non-IND studies) on file?		☐ Yes **(C)**	☐ No **(M)**
2.	Is the 1572 / Agreement current and accurate?		☐ Yes **(C)**	☐ * No **(L)**
3.	Does the 1572 / Agreement include a valid **signature & date** by the PI?		☐ Yes **(C)**	☐ No **(M)**
	TOTALS:		**C:**	**M:** **L:**
FINDINGS/CAP:				

LABORATORY NORMALS & ACCREDITAIONS ☐ **NA**				
1.	Are all required laboratory **CLIA(s) and CAP(s)** current and on file–or- is there an appropriate reference to the Central eReg ? • If not in central eReg but filed in the specific study eReg, are all previous ones filed (for duration of study)?	☐ NA	☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(M)** ☐ No **(L)**
2.	Is CV and medical license of Lab Director current and on file (to represent duration of study)? or- is there an appropriate reference to the Central eReg ?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
3.	Are normal ranges for all protocol-required tests on file? or- is there an appropriate reference to the Central eReg ?	☐ NA	☐ Yes **(C)**	☐ No **(M)**

		TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:				

SPECIMEN PROCESSING ☐ **NA**			
1.	Are **specimen processing** (e.g. tumor blocks, study kits) records on file? or- is there an appropriate reference in a NTF/Kept elsewhere.	☐ Yes **(C)**	☐ No **(M)**
2.	Are shipping documents for research specimens accurate and on file?	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

STUDY PERSONNEL SIGNATURE / RESPONSIBILITY LOG			
1.	Is there a Site Signature Delegation of Authority Log (**SSDOA**) on file -or completed **DOA log** in Clinical.ly?	☐ Yes **(C)**	☐ No **(M)**
2.	Does the SSDOA/DOA contain all study **personnel and appropriate delegated tasks**?	☐ Yes **(C)**	☐ No **(M)**
3.	Is the SSDOA/DOA **complete** with name, title, signature, initials, delegated tasks, start date and end date (or other protocol-specific items) with PI sign off?	☐ Yes **(C)**	☐ No **(L)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

PROTOCOL TRAINING LOG			
1.	Is there a **Protocol Training Log** on file- or completed via Clinical.ly features?	☐ Yes **(C)**	☐ No **(M)**
2.	Does the Log contain **all study personnel**? • Are all applicable staff listed? • Are all protocol versions listed?	☐ Yes **(C)** ☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(L)** ☐ No **(L)** ☐ No **(L)**
3.	Are other trainings required and listed accordingly? ICF? eCRFs? Etc. ☐NA • Are all staff listed?	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

SITE MONITORING LOG & REPORTS ☐ **NA (investigator-initiated)**			
1.	Is the **Site Monitoring Log** on file? Is it complete?	☐ Yes **(C)**	☐ No **(L)**
2.	Are copies of all Monitoring Reports on file? • Were reports forwarded to RQAP per Policy?	☐ Yes **(C)**	☐ No **(L)**
3.	Did each monitor sign a confidentiality statement (if applicable)? ☐NA	☐ Yes **(C)**	☐ No **(M)**
	TOTAL:	**C:**	**M:** **L:**

FINDINGS/CAP:

SCREENING / ENROLLMENT LOG			
1.	Is the **Screening/Enrollment Log** present & current? NTF present, if not? • If in Clinical.ly- is the document protected from others if PHI included?	☐ Yes**(C)**	☐ * No **(M)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

SUBJECT PAYMENT LOG ☐ NA			
1.	If required, is there a **Subject Payment Log** on file? For patient parking, stipends, etc.	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

IRB APPROVALS AND FINAL REPORTS (IRB and/or RA approval, as applicable)				
1.	Is the ***initial IRB*** *approval* for the protocol including the consent on file?		☐ Yes **(C)**	☐ No **(L)**
2.	If applicable, have all ***Amendments*** been submitted to the IRB and the IRB approvals are on file?	☐ NA	☐ Yes **(C)**	☐ * No **(M)**
3.	If applicable, have all Annual ***Continuation Reports*** been submitted to the IRB and the IRB approvals are on file?	☐ NA	☐ Yes **(C)**	☐ * No **(M)**
4.	If applicable, have all ***advertisements, recruitment materials, telephone scripts, and patient information*** been submitted to the IRB and IRB approvals are on file?	☐ NA	☐ Yes **(C)**	☐ * No **(M)**
5.	If applicable, has the *Study Closure Report* been submitted to the IRB and the IRB approval on file?	☐ NA	☐ Yes **(C)**	☐ * No **(M)**
	TOTALS:		**C:**	**M:** **L:**
FINDINGS/CAP:				

IRB MEMBERSHIP ☐ NA (external IRB of Record)				
1.	Is a current **IRB Membership** roster on file –or- is there an appropriate reference to the Central eReg ? - Are all previous Memberships on file (for duration of study) -or- is there an appropriate reference to the Central eReg?		☐ Yes **(C)** ☐ Yes **(C)**	☐ No **(M)** ☐ No **(L)**
2.	If any study personnel are members of the IRB, is there documentation that the member abstained from voting on this protocol and will abstain in any future voting?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:		**C:**	**M:** **L:**
FINDINGS/CAP:				

SERIOUS ADVERSE EVENTS / IND SAFETY REPORTS / UNANTICIPATED PROBLEM REPORTS				
1.	Are all **Unanticipated Problems** on file?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
2.	Are **IND Safety** Reports for this protocol on file? • Is there documentation of prompt PI review?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
3.	Have all IND safety Reports meeting criteria for an Unanticipated Problem been reported to the IRB?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:		**C:**	**M:** **L:**
FINDINGS/CAP:				

CORRESPONDENCE			
1.	Does the file contain all up-to-date **external correspondence** between the site and the sponsor (i.e., external correspondence)?	☐ Yes **(C)**	☐ No **(L)**
2.	Does the file contain all up-to-date **internal correspondence**?	☐ Yes **(C)**	☐ No **(L)**
	TOTAL:	**C:**	**M:** **L:**
FINDINGS/CAP:			

STUDY PRODUCT – ☐ Kept by Pharmacy-not audited ☐ NA			
1.	Are the study product accountability records accurate, current, and on file? or- is there an appropriate reference in a NTF/Kept elsewhere.	☐ Yes **(C)**	☐ No **(M)**
2.	Do the study product accountability records agree with the actual inventory on hand?	☐ Yes **(C)**	☐ No **(M)**
3.	Are instructions (protocol-specific) for the storage, mixing, and handling of study product easily accessible and on file?	☐ Yes **(C)**	☐ No **(M)**
4.	Are shipping records for study product documenting the receipt date, quantity, and lot numbers of all study products on file	☐ Yes **(C)**	☐ No **(M)**
5.	Is the randomization list and decoding procedures for blinded study product on file?	☐ Yes **(C)**	☐ No **(M)**
6.	Is the disposition of used and unused study products captured on the accountability logs?	☐ Yes **(C)**	☐ No **(M)**
7.	If applicable, are study product environment (e.g. temperature) logs on file?	☐ Yes **(C)**	☐ No **(M)**
8.	If applicable, is there an unblinding plan on file? Check eSM for plan.	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:	**C:**	**M:** **L:**
FINDINGS/CAP:			

PROTOCOL DEVIATIONS				
1.	Have all **Major Protocol Deviations** been reported according to RA Policies & SOPs? Check Major Deviation folder.	☐ NA	☐ Yes **(C)**	☐ No **(M)**
	TOTALS:		**C:**	**M:** **L:**
FINDINGS/CAP:				

SAMPLE CASE REPORT FORMS				
1.	Are sample CRFs, subject diaries, or other forms used for entering data on file in Miscellaneous or eSM folders?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
2.	For eCRF's is there documentation on file that a CD will be provided at the end of the study? If no record, ask CRC…	☐ NA	☐ Yes **(C)**	☐ No **(L)**
	TOTAL:		**C:**	**M:** **L:**
FINDINGS/CAP:				

CONFLICT OF INTEREST / FINANCIAL DISCLOSURE			
1.	Is a current Conflict of Interest/Financial Disclosure on file for the PI, each sub-investigator and study coordinator? May need to ask CRC/PI for records as these may not be kept in the eReg.	☐ Yes **(C)**	☐ No **(L)**
	TOTAL:	**C:**	**M:** **L:**

FINDINGS/CAP:

NOTES TO FILE				
1.	Does the file contain relevant Notes To File?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
2.	Are the Notes To File completed according to RA Policies and SOPs?	☐ NA	☐ Yes **(C)**	☐ No **(M)**
		TOTAL:	**C:**	**M:** **L:**
FINDINGS/CAP:				

OTHER FINDINGS:

SCORE: Total # **Compliant** Items:
Total # **Lesser** noncompliance(s):
Total **# Major** noncompliance(s):

FINAL ASSESSMENT:

☐ **Exceptional:** Demonstrates superior regulatory documentation and record maintenance fully aligned with Research Administration Policies and SOPs.

☐ **Satisfactory:** Generally compliant with all Research Administration Policies and SOPs. Minor noncompliance issues may be present, and/or any major issues previously identified were fully corrected and documented prior to the audit, requiring no further action.

☐ **Acceptable Needs Follow-up:** Displays inconsistent adherence to Research Administration Policies and SOPs or incomplete records. Multiple minor noncompliance issues and/or a small number of major issues were identified that were not addressed prior to the audit.

☐ **Unacceptable Needs Follow-up:** Multiple major noncompliance issues or non-compliant categories identified; or a single major, flagrant noncompliance; or an excessive number of minor or recurring noncompliance issues. Findings suggestive of disregard for regulatory safeguards.

Additional notes:

Document Attributes

Title	Internal Audit Tool- Regulatory		
Author (s)	Stephanie Scala, MA, CCRP Manager, Research Quality Assurance Program	**Date of Origin**	February 19, 2019
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Approved	**Signature on File** Stephanie Scala, MA, CCRP Manager, Research Quality Assurance Program