

Operations Manual

Document: Internal Audit Tool-Subject Files

Overview

Institution:	Protocol:
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

INFORMED CONSENT – FORMS, PROCESS & DOCUMENTATION			
1.	Is there a consent form(s) in the patient research files and scanned into the medical record?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
2.	Are all required signatures and dates completed?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (L)
3.	Was the version of the consent form used to consent the subject valid at the time of consent? ICF exp. date: _____ Date consent signed: _____	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
4.	Was the consent signed and dated by the subject, parent/guardian, and/or legally acceptable representative (LAR) PRIOR to implementation of screening/protocol-specific procedures?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
5.	If applicable, was Re-Consent obtained and/or "New Information" provided as required and documented in patient research files and medical record?	<input type="checkbox"/> NA Yes (C)	<input type="checkbox"/> No (M)
6.	Is there documentation (e.g. Consent Progress Note) describing the informed consent process and discussion, including: a. An explanation of the study and confidentiality of information b. Ample opportunity to make decision, ask questions and provide answers c. Copy of consent given to subject, parent/guardian, or LAR	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
7.	Was the consent obtained in a language fully understood by the subject?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
8.	If an alternative consent method was required (e.g. subject unable to read or sign, non-English speaking subject, emergency use), was the appropriate SOP followed?	<input type="checkbox"/> NA Yes (C)	<input type="checkbox"/> No (M)
TOTALS:		C:	M: L:
FINDINGS/CAP:			

ELIGIBILITY – INCLUSION/EXCLUSION CRITERIA

1.	Is there documentation of all eligibility criteria (inclusion/exclusion) in the source documents? (Criteria must be itemized; a blanket statement is not acceptable)	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	* No (M)
2.	Review of source documents confirms that subject met all eligibility criteria per IRB approved protocol in effect at time of enrollment?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (M)
3.	Is eligibility criteria documentation signed and dated by an investigator approved by the IRB for the study prior to randomization/treatment?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (L)
4.	Is the investigator listed on the SSSDOA Log?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (L)
5.	<input type="checkbox"/> Device study = NA <input type="checkbox"/> Drug study: Is the investigator listed on the 1572?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (L)
6.	If applicable, was an Enrollment Exception requested & received from the IRB PRIOR to enrollment?	<input type="checkbox"/>	<input type="checkbox"/>
		NA	Yes (C) No (M)
TOTALS:		C:	M: L:
FINDINGS/CAP:			

EMR LINKING REQUIREMENTS			
1.	Was the subject linked to the study in Epic? Is enrollment status current?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (M)
		<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (L)
2.	Were all relevant study appointments linked to the study?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	* No (L)
3.	If unable to link previous subjects, can the investigator now link new enrolled subjects?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	* No (L)
4.	Was the subject linked to the study calendar?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (L)
TOTALS:		C:	M: L:
FINDINGS/CAP:			

PRE-THERAPY – (See study schematic)			
1.	Is there accurate documentation of initial/baseline disease site/status according to protocol?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	* No (M)
2.	Were all pre-therapy tests of major importance (e.g. baseline CT scan to document pre-therapy tumor size in oncology study) done PRIOR to therapy?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	* No (M)
3.	Was the protocol-specified timeframe adhered to?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	No (L)
TOTALS:		C:	M: L:
FINDINGS/CAP:			

* Missing few minor tests = (L)

ENROLLMENT/RANDOMIZATION/STRATIFICATION			
1.	Is subject enrollment/randomization documented accurately (e.g. date of birth, date of diagnosis, lab values and dates are consistent as well as stage, diagnosis, cell type, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>
		Yes (C)	* No (M)
2.	Was subject randomized/registered prior to treatment?	<input type="checkbox"/>	<input type="checkbox"/>

		Yes (C)	No (M)
3.	Was the protocol-specified timeframe adhered to?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
TOTALS:		C:	M: L:
FINDINGS/CAP:			

* Wrong date of birth, date of diagnosis, lab values or inconsistent dates may = (L)

STUDY DRUG(S) – TREATMENT <input type="checkbox"/> NA			
List study drug(s):			
1.	Was the drug(s) dispensed upon order of an investigator (or designee) listed on the 1572?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
2.	Is there documentation of drug dose and timing for each administration?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
3.	Was the correct drug(s) used?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
4.	Was the correct route used?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
5.	Were all treatment doses correctly administered, calculated and documented?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
6.	Were concomitant medications documented accurately per protocol?	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
7.	Were all additional (non-study) drugs used/taken permitted by the protocol?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C) * No (M)
8.	Is there documentation of evaluation of dose modification/toxicity criteria for each dose administration?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C) * No (M)
9.	Were all dose modifications made when required and according to protocol?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C) * No (M)
10.	If the dose was modified, was the calculation correct?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C) * No (M)
11.	If protocol has toxicity criteria for dose modification or delay, were toxicities evaluated prior to each dose? If severe toxicity occurred, was dose reduced or held per protocol?	<input type="checkbox"/> NA	<input type="checkbox"/> * No (M) <input type="checkbox"/> No (M) Yes (C) Yes (C)
12.	Was the timing of drug administration/cycle correct per protocol?	<input type="checkbox"/> NA	<input type="checkbox"/> * No (M) Yes (C)
13.	For dose-intensity study, was the dose escalated and/or reduced per protocol?	<input type="checkbox"/> NA	<input type="checkbox"/> * No (M) Yes (C)
14.	If the drug was held, is there documentation of the reason?	<input type="checkbox"/>	<input type="checkbox"/> *

		Na	Yes (C)	No (M)
15.	Is there documentation of instructions given to the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *
		NA	Yes (C)	No (M)
16.	Is there documentation of subject compliance (e.g. pill counts and diary)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *
		NA	Yes	No (M)
17.	Is there documentation of return of unused study drug to pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *
		NA	Yes	No (M)
TOTALS:			C:	M: L:
FINDINGS/CAP:				

* Wrong antiemetic/pre-meds, < 5% deviation without explanation for one wrong dose; 5% deviation from dose reduction indicated; wrong timing delay with acceptable explanation (i.e. holiday, bad weather) = (L)

STUDY DEVICE(S) – TREATMENT <input type="checkbox"/> NA				
List study device(s):				
1.	Was the device(s) dispensed upon order of an investigator (or designee) listed on the Clinical Trial Agreement?	<input type="checkbox"/>	<input type="checkbox"/>	
		Yes (C)	No (M)	
2.	Is there documentation of device accountability?	<input type="checkbox"/>	<input type="checkbox"/>	
		Yes (C)	No (M)	
3.	If device was explanted, were proper procedures followed? NA	<input type="checkbox"/>	<input type="checkbox"/>	
		Yes (C)	No (M)	
TOTALS:			C:	M: L:
FINDINGS/CAP:				

DISEASE OUTCOME/RESPONSE <input checked="" type="checkbox"/> NA				
1.	Is response to treatment assessed/evaluated according to protocol guidelines?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *
		Yes (C)	No (M)	
2.	Are tumor measurements/evaluations of status (e.g., baseline CT scan) or disease performed according to protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *
		NA	Yes (C)	No (M)
3.	Is response to treatment evaluated according protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *
		NA	Yes (C)	No (M)
4.	Is assessment of response to treatment (e.g. tumor response) accurate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> *

		NA	Yes (C)	No (M)
TOTALS:			C:	M: L:
FINDINGS/CAP:				

* Missing minor measurements or one of several minor measurements used to assess response = (L)

PROTOCOL EVENTS – VISITS, EVALUATIONS, TESTS, STUDY KITS, SPECIMEN PROCESSING (See study schematic)				
1.	Were all protocol-required visits completed to date? <i>Within window? (L)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
			Yes (C)	
2.	Were all protocol-required diagnostic tests (other than labs) completed to date? <i>Within window? (L)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
			Yes (C)	
3.	Were all protocol-required laboratory tests and/or study kits completed to date? <i>Within window? (L)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
			Yes (C)	
5.	Were all abnormal test results assessed for AE grade and attribution?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (L)
		NA	Yes (C)	
6.	Were all specimens (e.g. serum, tissue) samples submitted as required (and if consented to) and within protocol-specified timeframe?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		NA	Yes (C)	No (M)
TOTALS:			C:	M: L:
FINDINGS/CAP:				

* Acceptable level of missing documentation with explanation; minor and sporadic missing tests; few errors in submitted data = (L)

ADVERSE EVENTS				
1.	Were all baseline studies obtained to effectively assess future toxicity/AEs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
			Yes (C)	
2.	Are all changes to subject's condition and/or lab abnormalities identified and assessed as AEs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (L)
		NA	Yes (C)	
3.	Are all AEs assessed for clinical significance and/or severity (e.g., graded) and documented in the source documents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
		NA	Yes (C)	
4.	Are all AEs assessed for relationship (e.g., attribution) to the study product and documented in the source documents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
		NA	Yes (C)	
5.	Are all AEs identified in the protocol as critical to safety evaluations/dose modifications assessed, acted upon as required, and documented in the source documents?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
		NA	Yes (C)	
6.	Are all identified open AEs followed and assessed at subsequent visits through resolution or until NA?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> * No (M)
		NA	Yes (C)	

7.	CTCAE grade criteria for reporting AEs: Grade __ -- __ Were all applicable AEs reported?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
8.	Were all AEs meeting the criteria for SAE reported to the sponsor following protocol-specified timelines and requirements?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
9.	Were all SAEs meeting the criteria for Unanticipated Problem (internal & external) reported to the IRB following the LHMC Policy and SOP? (e.g. ,criteria met, timeliness met)	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
TOTALS:			C:	M: L:
FINDINGS/CAP:				

* Not reporting one grade 3 unexpected toxicity or not reporting toxicities within required time line = (L)

DATA MANAGEMENT				
1.	Are subject patient research files complete, accurate and available?		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
2.	Is all source documentation complete, accurate and available?		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
3.	Are source documents scanned into the medical record?		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
4.	Are all data corrections and/or addenda made correctly?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
5.	Are all handwritten notes legible, signed and dated?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
6.	Are all Notes To File documented according to the Lahey SOP?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
7.	Are all CRFs to date present?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
8.	For eCRFs – are there copies of completed eCRFs? If not, is there documentation that the Sponsor will provide a CD copy for site records?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
9.	Does the CRF/eCRF data and source documentation data match?		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
10.	If any CRF is used as a source document, is the CRF identified as such in the protocol? a. Is the CRF signed and dated?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
		<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (L)
11.	Were all the CRFs submitted within 2 months of data capture? If no, timeframe of most delinquent CRF <input type="checkbox"/> 3-6 mo. (Lesser def.) <input type="checkbox"/> > 6 mo.(Major def.)		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
12.	Have all data queries been addressed?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> * No (M)
TOTALS:			C:	M: L:
FINDINGS/CAP:				

PROTOCOL DEVIATIONS		Not assessed		
1.	Have all Protocol Deviations been reported according to LHMC Policies and SOPs?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
2.	Did any deviations occur? <input type="checkbox"/> Yes <input type="checkbox"/> No a. If Yes, is deviation documented in source documentation? b. If Yes, has Protocol Deviation Report been submitted?		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
			<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
		TOTALS:	C:	M: L:
FINDINGS/CAP:				

Insurance		<input type="checkbox"/> Not assessed		
1.	His the patient on Medicaid/ MassHealth (for patients enrolled after 11/1/22)?	<input type="checkbox"/> NA	<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (M)
2.	Did the PI sign the Medicaid Attestation Form on the Appropriateness of a Qualifying Clinical Trial?		<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
			<input type="checkbox"/> Yes (C)	<input type="checkbox"/> No (L)
		TOTALS:	C:	M: L:
FINDINGS/CAP:				

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

FINAL ASSESSMENT:

Exceptional: Demonstrates superior source documentation, high-quality data, 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 corrected 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.

Unacceptable Needs Follow-up: Multiple major noncompliance issues or non-compliant categories identified; a single major flagrant noncompliance; an excessive number of 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.

Additional notes:

Document Attributes

Title	Internal Audit Tool- Subject Files		
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		