

Clinical Trials Monitoring Branch Final Report

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Date:

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Audit Date:

Group :

Audit Category:

Audit Type:

Institution NCI Code:

Name:

Audit Location:

Date of Prior Audit:

Number of Cases Audited:

Average Annual Accrual:

Principal Investigator:

Institution Roster Detail

Institution NCI Code	Institution Name	Role
		Main Member
		Affiliate

Audit Outcome Summary

Component	Assessment	Follow up Required (Y/N)	Follow up Due Date	Reaudit Required (Y/N)	Reaudit Time (in months)
IRB and Informed Consent Content Review	Acceptable needs follow-up				
Accountability of Investigational Agents	Acceptable				
Patient Case Review	Unacceptable				

Reaudit Timeline History

Component	Reaudit Time	Reaudit CTMB Comments
IRB Reaudit Time Line History		
Pharmacy Reaudit Time Line History		
Patient Case Reaudit Time Line History		

Institution Staff	Title	Affiliation
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Audit Team	Title	Affiliation
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IRB Review

Protocol#	# of Patients	IND or NCI Supplied Agents	Diseases	CTMB Guidelines Deficiency Major / Lesser	Overall IRB Deficiency	Description of Deficiency and Comments
					Major	<p>Overall Comments for IRB deficiencies:</p> <p>Deficiency:</p> <ul style="list-style-type: none"> - Protocol never approved by IRB COMMENTS: - Initial IRB approval documentation missing COMMENTS: - Initial approval by expedited review COMMENTS: - Expedited reapproval for situations other than approved exceptions COMMENTS: - Registration and/or treatment of patient prior to full IRB approval COMMENTS: - Reapproval delayed greater than 30 days but less than one year COMMENTS: - Registration of patient on protocol during a period of delayed reapproval or during a temporary suspension (ie, Request for Rapid Amendment) COMMENTS: - Missing reapproval COMMENTS: - Expired reapproval COMMENTS: - Internal reportable adverse event reported late or not reported to IRB COMMENTS: - Lack of documentation of IRB approval of a protocol amendment that affects more than minimal risk or IRB approval

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IRB Review

Protocol#	# of Patients	IND or NCI Supplied Agents	Diseases	CTMB Guidelines Deficiency Major / Lesser	Overall IRB Deficiency	Description of Deficiency and Comments
						<p>is greater than 90 days after Network Group's notification; this includes a 'Request for Rapid Amendment (RRA)' resulting from an Action Letter indicating temporary suspension of accrual with expedited review permitted</p> <p>COMMENTS:</p> <ul style="list-style-type: none"> - Failure to submit or submitted after 90 days, any reportable external safety report to the IRB that is considered an unanticipated problem as defined by OHRP <p>COMMENTS:</p> <ul style="list-style-type: none"> - Protocol reapproval delayed 30 days or less <p>COMMENTS:</p> <ul style="list-style-type: none"> - Delayed reapproval for protocol closed to accrual for which all patients/study participants have completed therapy <p>COMMENTS:</p> <ul style="list-style-type: none"> - Other deficiencies found for IRB <p>COMMENTS:</p> <ul style="list-style-type: none"> - Other Deficiency Rating: Major

Total# of Patients:	Total Protocols Reviewed:	Total Major/Protocol(s):	Total Lesser/Protocol(s):
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* after Protocol# indicates that Informed Consent Content was reviewed for that protocol

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Informed Consent Content (ICC) Review

Protocol#	Number of Missing/Incomplete Elements from ICC	Overall ICC Deficiency Major	Description of Missing/Incomplete Elements and Comments
			<p>Overall Comments for ICC deficiency:</p> <p>Deficiency:</p> <ul style="list-style-type: none"> - Involves research: purposes; duration of participation; description of procedures; identification of experimental procedures COMMENTS: - Description of risks or discomforts COMMENTS: - Description of any benefits to subject or others COMMENTS: - Disclosure of alternative procedures or treatments COMMENTS: - Description of the extent of confidentiality of records COMMENTS: - Explanation regarding compensation and/or whether treatments are available if injury occurs COMMENTS: - Explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject COMMENTS: - Participation is voluntary; refusal to participate involves no penalty; subject may discontinue participation at any time COMMENTS: - Unforeseeable risks to subject, embryo or fetus COMMENTS: - Circumstances in which subject's participation may be terminated by investigator without subject's consent COMMENTS: - Additional costs to subject which may result from participation in research COMMENTS: - Consequences of subject withdrawal and procedures for orderly termination of participation by subject COMMENTS:

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Informed Consent Content (ICC) Review

Protocol#	Number of Missing/Incomplete Elements from ICC	Overall ICC Deficiency	Description of Missing/Incomplete Elements and Comments
			<ul style="list-style-type: none"> - Statement that new findings which may relate to subject's willingness to continue participation will be provided to subject COMMENTS: - Disclosure of approximate number of participants COMMENTS: - Statement stating: "A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time." COMMENTS: - Statement that a copy of the consent will be given to participant COMMENTS: - Other deficiencies found for ICC COMMENTS:

Total# of Patients:

Total Protocols Reviewed:

Total Major/Protocol(s):

Total Lesser/Protocol(s):

IRB and Informed Consent Content Assessment

IRB and Informed Consent Content assessment: Acceptable needs follow-up

Follow-up required for IRB deficiency: Yes COMMENTS:

Follow-up required for Informed Consent Content deficiency: Yes COMMENTS:

Re-audit required for IRB and Informed Consent Content section: Yes

Re-audit Reason:

Re-audit required (in months):

Overall Comments:

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Audit Location:

Pharmacy Review

Were INDs or NCI supplied agents used at this site during the period covered by this audit: Yes

Drug accountability checked during this audit: Yes

Protocol#	Number of NCI DARFs compared to shelf inventory	Number of patients cross checked with NCI

Compliant

[]

Non-Compliant

[X]

Not Reviewed

[]

NCI DARFs Completely and Correctly Filled Out

Protocol

Non-Compliant

COMMENTS:

Deficiency:

- NCI DARF not maintained or not maintained completely and accurately
- Oral NCI DARF not maintained or not completely and accurately filled out
- NCI DARF not maintained on a timely basis
- Inability to track the receipt, use and disposition of NCI-supplied study agents
- Incorrect agent, dose, or dates dispensed, incorrectly prepared drug, and/or incorrectly documented
- Paper and/or electronic DARFs (eDARFs) do not contain all information or are not completed as required; paper printout of eDARF is not identical to the NCI DARF
- Erasures or "whiteouts" on paper DARF
- Corrections are not lined out, initialed and dated on paper DARF
- Corrections are not appropriately documented on eDARF in electronic inventory system
- Agent has been transferred to an investigator who is not actively registered with CTEP
- NCI-supplied study agents are repackaged and/or reshipped to other investigators, patients, or locations by mail or express carrier
- Dispensing of NCI-supplied study agent to a registered patient/study participant and not recorded or not recorded on the appropriate DARF

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Audit Location:

Compliant

Non-Compliant

Not Reviewed

NCI DARFs Protocol and Agent specific

Protocol Non-Compliant

COMMENTS:

- Deficiency:**
- Patient/study participant identified on DARF is not a registered patient/study participant
 - NCI-supplied study agent used for pre-clinical or laboratory studies without written approval by NCI
 - Substitution of any NCI-supplied study agent, with non-NCI supplied study agent, including commercial agents
 - Lack of a DARF(s) to verify NCI-supplied study agents are administered to patients/study participants or transported and delivered to investigators at Satellite Dispensing Areas and administered to patients/study participants
 - Each NCI-supplied study agent not accounted for separately by protocol
 - DARF maintained by lot #
 - One DARF used for more than one protocol
 - One DARF used for a protocol using multiple study agents
 - One DARF used for multiple strengths, dosage forms of an agent, or multiple ordering investigators
 - Single DARF used for multiple patients/study participants on study when patient-specific DARF should be maintained
 - Multiple dose vials recorded for one patient/study participant instead of multiple patients/study participants, or multiple doses recorded on a single line of the DARF

Satellite of Records Dispensing Area

Protocol Non-Compliant

COMMENTS:

- Deficiency:**
- No satellite DARFs in use when required
 - Satellite DARFs not available at the time of the audit
 - Satellite and Control records do not match or are not accurately maintained
 - Unused study agent is not documented or returned to Control dispensing area; Satellite Dispensing Area is inappropriately transferring and/or locally destroying NCI-supplied study agent

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Audit Location:

Pharmacy Assessment

Pharmacy Assessment: Acceptable

Follow-up Required: Yes

COMMENTS:

Re-audit Required: Yes

Re-audit Reason:

Re-audit Required (in months):

Pharmacy Narrative:

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Audit Type:

Patient Case Review

Protocol#	Patient#	Category	Result	Description of Deficiency and Comments
			OK	<p>- OVERALL COMMENTS: Deficiency:</p> <ul style="list-style-type: none"> - Consent form document missing COMMENTS: - Consent form document not signed and dated by the patient/study participant COMMENTS: - Translated consent or short form not signed and dated by a non-English speaking patient/study participant COMMENTS: - Consent form not signed by patient prior to study registration/enrollment COMMENTS: - Consent form does not contain all required signatures COMMENTS: - Consent form used was not the current IRB-approved version at the time of patient registration COMMENTS: - Consent form not protocol specific COMMENTS: - Consent form does not include updates or information required by IRB COMMENTS: - Re-consent not obtained as required COMMENTS: - Other deficiencies found for Informed Consent COMMENTS:
		Eligibility	OK	<p>- OVERALL COMMENTS: Deficiency:</p> <ul style="list-style-type: none"> - Review of documentation available at the time of the audit confirms patient/study participant did not meet all eligibility criteria and/or eligibility requirements were not

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Patient Case Review

Protocol#	Patient#	Category	Result	Description of Deficiency and Comments
				<p>obtained within the timeframe as specified by the protocol</p> <p>COMMENTS:</p> <ul style="list-style-type: none"> - Documentation missing; unable to confirm eligibility <p>COMMENTS:</p> <ul style="list-style-type: none"> - Other deficiencies found for Eligibility <p>COMMENTS:</p> <ul style="list-style-type: none"> - Rating: Lesser
		Treatment	OK	<p>- OVERALL COMMENTS:</p> <p>Deficiency:</p> <ul style="list-style-type: none"> - Incorrect agent/treatment/intervention used <p>COMMENTS:</p> <ul style="list-style-type: none"> - Additional agent/treatment/intervention used which is not permitted by protocol <p>COMMENTS:</p> <ul style="list-style-type: none"> - Dose deviations, modifications, or incorrect calculations (error greater than +/- 10%) <p>COMMENTS:</p> <ul style="list-style-type: none"> - Dose modifications/treatment interventions not per protocol <p>COMMENTS:</p> <ul style="list-style-type: none"> - Treatment/intervention incorrect or not administered correctly, incorrectly calculated, or not adequately documented <p>COMMENTS:</p> <ul style="list-style-type: none"> - Timing and sequencing of treatment/intervention not per protocol <p>COMMENTS:</p> <ul style="list-style-type: none"> - Unjustified delays in treatment/intervention <p>COMMENTS:</p> <ul style="list-style-type: none"> - Other deficiencies found for Treatment <p>COMMENTS:</p> <ul style="list-style-type: none"> - Rating: Major

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Patient Case Review

Protocol#	Patient#	Category	Result	Description of Deficiency and Comments
		Disease Outcome/Response	OK	<p>-OVERALL COMMENTS:</p> <p>Deficiency:</p> <ul style="list-style-type: none"> - Inaccurate documentation of initial sites of involvement COMMENTS: - Tumor measurements/evaluation of status or disease not performed or not documented according to protocol COMMENTS: - Protocol-directed response criteria not followed COMMENTS: - Claimed response (PR, CR, etc.) cannot be verified or auditor could not verify the reported response COMMENTS: - Failure to detect cancer (as in a prevention study) or failure to identify cancer progression COMMENTS: - Other deficiencies found for Disease Outcome/Response COMMENTS: <ul style="list-style-type: none"> - Rating: Major
		Adverse Event	OK	<p>-OVERALL COMMENTS:</p> <p>Deficiency:</p> <ul style="list-style-type: none"> - Grades, types, or dates/duration of serious adverse events inaccurately recorded COMMENTS: - Adverse events cannot be substantiated COMMENTS: - Follow-up studies necessary to assess adverse events not performed COMMENTS: - Failure to report or delayed reporting of an adverse event that would require filing an expedited Adverse Event (AE) report or reporting to the Group COMMENTS:

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Patient Case Review

Protocol#	Patient#	Category	Result	Description of Deficiency and Comments
				<ul style="list-style-type: none"> - Recurrent under- or over-reporting of adverse events COMMENTS: - Other deficiencies found for Adverse Events COMMENTS: <li style="padding-left: 20px;">- Rating: Major
		General Data Management Quality	OK	<ul style="list-style-type: none"> - OVERALL COMMENTS: Deficiency: - Recurrent missing documentation in the patient/study participant records COMMENTS: - Protocol specified laboratory tests not reported or not documented COMMENTS: - Protocol-specified diagnostic studies including baseline assessments not done, not reported or not documented COMMENTS: - Protocol-specified research/advanced imaging studies not done or submitted appropriately COMMENTS: - Frequent data inaccuracies COMMENTS: - Errors in submitted data COMMENTS: - Delinquent data submission (> 6 month delinquency is considered a major deficiency; a 3-6 month delinquency is considered a lesser deficiency) COMMENTS: - Other deficiencies found for General Data Management Quality COMMENTS: <li style="padding-left: 20px;">- Rating: Lesser

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Patient Case Review

Protocol#	Patient#	Informed Consent	Eligibility	Treatment	Adverse Event	Disease Outcome / Response	General Data Management Quality

Total # of Patient cases: _____
 Total # of Major deficiencies: _____
 Total # of Lesser deficiencies: _____
 Total # of items Not Reviewed: _____

Patient Case Review Assessment

Patient Case Review Assessment: Unacceptable
Follow-up required for Informed Consent Content: Yes COMMENTS: '
Follow-up required for Eligibility: Yes COMMENTS: '
Follow-up required for Treatment: Yes COMMENTS: '
Follow-up required for Disease Outcome/Response: Yes COMMENTS: '
Follow-up required for Adverse Event: Yes COMMENTS: '
Follow-up required for General Data Management Quality: Yes COMMENTS: '
Reaudit required: Yes
Reaudit Reason: _____
Reaudit required (in months): _____

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Audit Type:

Audit Procedures:
General Comments:
Exit Interview Comments:

Prepared By

Date

Approved By

Date