Clinical Trials Monitoring Branch - Final Report

Run By :

Date:

Audit Date : **Group :** **Audit Category :** **Audit Type :**

Institution Code : **Name :**

Main Member / CCOP Code : ***Name :***

Audit Location :

Date of Prior Audit : **Number of Cases Audited :** **Average Annual Accrual :** **Principal Investigator :**

Audit Outcome Summary

Component	Assessment	Followup Required (Y/N)	Followup Due	Reaudit Required (Y/N)	Reaudit Time (in months)
IRB and Informed Consent Content Review					
Accountability of Investigational Agents and Pharmacy Operations Review					
Patient Case Review					

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

Audit Team	Title	Affiliation

Co-site Visitor	Title	Affiliation

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IRB Review

Protocol #	# of Patients	INDs or NCI Supplied Agents	Diseases	CTMB Guidelines Deficiency Major/Lesser	Overall IRB Deficiency	Description of Deficiency and Comments

Deficiency:

Total # of Patients : Total Protocols Reviewed : Total Major/Protocol(s) : Total Lesser/Protocol(s) :

* after Protocol # indicates that Informed Consent Content was reviewed for that Protocol

Total # of CTSU Patients : Total CTSU Protocols Reviewed: Total CTSU Major/ Protocol(s) : Total CTSU Lesser/ Protocol(s):

Informed Consent Content (ICC) Review

Protocol #	Number of Missing/Incomplete Elements from ICC	Overall ICC Deficiency	Description of Missing/Incomplete Elements and Comments

Deficiency:

Total # of Patients : Total Protocols Reviewed : Total Major/Protocol(s) : Total Lesser/Protocol(s) :

Total # of CTSU Patients : Total CTSU Protocols Reviewed : Total CTSU Major/ Protocol(s): Total CTSU Lesser/ Protocol(s):

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IRB and Informed Consent Content Assessment

IRB and Informed Consent Content Assessment :

Follow-up required for IRB deficiency : COMMENTS :

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

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

Re-audit Reason :

Re-audit required (in months) :
Overall Comments:

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Audit Location :

Accountability of Investigational Agents and Pharmacy Operations Review

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

Drug accountability checked during this audit :

Number of NCI DARFs compared to shelf inventory :

Number of patients cross checked with NCI :

List Of Protocols Reviewed for Pharmacy:

Compliant	Non-Compliant	Not Reviewed	
[ ]	[ ]	[ ]	NCI DARFs completely and correctly filled out
			Protocol Deficiency: Non-compliant COMMENTS:
[ ]	[ ]	[ ]	NCI DARFs were protocol and drug specific
[ ]	[ ]	[ ]	Satellite records accounted for
[ ]	[ ]	[ ]	NCI DARFs kept as primary transaction record
[ ]	[ ]	[ ]	Return of drug to NCI
[ ]	[ ]	[ ]	Agent(s) stored by protocol
[ ]	[ ]	[ ]	Adequate Security

Pharmacy Narrative :

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Audit Location :

Accountability of Investigational Agents and Pharmacy Operations Assessment

Accountability of Investigational Agents and Pharmacy Operations Assessment :

Follow-up Required :

Re-audit Required :

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Audit Location :

Patient Case Review

Protocol #	Patient #	Category	Result	Description of Deficiency and Comments
		Informed Consent		
				Deficiency:
		Eligibility		
		Treatment		
		Disease Outcome/Response		
		Adverse Event		
		General Data Management Quality		

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Institution Code : Name :

Main Member / CCOP Code : *Name :*

Audit Location :

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

Total # of Major deficiencies : _ Total # of Lesser deficiencies : _ Total # of deficiencies Not Reviewed : _

Total # of Patient cases : Total # of Patient cases :

Total # of CTSU Major deficiencies :_ Total # of CTSU Lesser deficiencies : _ Total #of CTSU deficiencies Not Reviewed:

Total # of CTSU Patient cases : Total # of CTSU Patient Cases :

Patient Case Review Assessment

Patient Case Review Assessment :

Follow-up required for Informed Consent : COMMENTS :

Follow-up required for Eligibility :

Follow-up required for Treatment :

Follow-up required for Disease Outcome/Response :

Follow-up required for Adverse Event :

Follow-up required for General Data Management Quality :

Re-audit required :

Audit Procedures :

General Comments :

Exit Interview Comments :

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Audit Location :			

Prepared By **Date**

Approved By **Date**