Clinical Trials Monitoring Branch - Final Report

Date:

Run By :

Audit Date : Group : Audit Category : Audit Type :
Institution Code : Name : Member Study Type:
Main Member / CCOP Code : *Name :*
Audit Location :
Revision Number: Revision Date:

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 Change History

Component	Reaudit Time	Reaudit CTMB Comments

Institution Staff	Title	Affiliation

Audit Team	Title	Affiliation

Co-site Visitor	Title	Affiliation

IRB Review

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

Clinical Trials Monitoring Branch - Final Report

Date:

Run By :

Audit Date :
Group :
Audit Category :
Audit Type :
Institution Code :
Name :
Member Study Type:
Main Member / CCOP Code :
Name :
Audit Location :
Revision Number:
Revision Date:

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

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

Informed Consent Content (ICC) Review

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

Follow-up required for IRB deficiency :

Follow-up required for Informed Consent Content deficiency :

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

Overall Comments:

Audit Date :
Group :
Audit Category :
Audit Type :
Institution Code :
Name :
Member Study Type:
Main Member / CCOP Code :
Name :
Audit Location :
Revision Number:
Revision Date:

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 :

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

Pharmacy Narrative :

Accountability of Investigational Agents and Pharmacy Operations Assessment

Accountability of Investigational Agents and Pharmacy Operations Assessment :

Follow-up Required :

Re-audit Required :

Clinical Trials Monitoring Branch - Final Report

Date:

Run By :

Audit Date : **Group :** **Audit Category :** **Audit Type :**
Institution Code : **Name :** **Member Study Type:**
Main Member / CCOP Code : ***Name :***
Audit Location :
Revision Number: **Revision Date:**

Patient Case Review

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

Clinical Trials Monitoring Branch - Final Report

Date:

Run By :

Audit Date : Group : Audit Category : Audit Type :

Institution Code : Name : Member Study Type:

Main Member / CCOP Code : *Name :*

Audit Location :

Revision Number: Revision Date:

Protocol #	Patient #	Informed Consent	Eligibility	Treatment	Toxicity	Disease Outcome	Data Quality

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

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

Patient Case Review Assessment

Patient Case Review Assessment :

Follow-up required for Informed Consent :

Follow-up required for Eligibility :

Follow-up required for Treatment :

Follow-up required for Disease Outcome/Response :

Follow-up required for Toxicity :

Follow-up required for General Data Quality :

Re-audit required :

Re-audit Reason :

Re-audit required (in months) :

Audit Procedures :

General Comments :

Run By :

Date:

Audit Date : Group : Audit Category : Audit Type :

Institution Code : Name : Member Study Type:

Main Member / CCOP Code : *Name :*

Audit Location :

Revision Number: Revision Date:

Exit Interview Comments :

Prepared By Date

Approved By Date