APPENDIX 6

Clinical Trials Monitoring Branch

Final Audit Report

This is a sample report. The actual report will be computer generated and may vary slightly in format.

National Cancer Institute
Clinical Trial[illegible]onitoring Branch
Fina[illegible]t Report

Audit Date: Group:

Institution Code: Institution: City: State:

Location of Site Visit:

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

Institution Staff	Title

Audit Team	Title and Affiliation

Co-Site Visitor	Affiliation

National Cancer Institute
Clinical Trials Monitoring Branch
Fin: 'it Report

I. IRB AND INFORMED CONSENT CONTENT REVIEW

A. IRB Review

Protocol	# of Pat.	IND Drugs/ Treatment Modalities	Disease	IRB Deficiency Description	IRB Deficiency (None, Major, Lessor)	Comments

B. Informed Consent Content Review

Informed consents contained all elements as required by Federal regulations and the risks/benefits listed in model informed consent.

- ☐ Yes
- ☐ No: Explain _____

C. IRB and Informed Consent Content Assessment

_____ Acceptable

_____ Acceptable Needs Follow-up

_____ Unacceptable

D. Reaudit required: No _____ Yes _____ Within _____ months

II. ACCOUNTABILITY OF INVESTIGATIONAL AGENTS AND PHARMACY OPERATIONS

Were INDs or NCI supplied agents used at this site during the period covered by this audit?
Y _____ N _____

Was Drug accountability checked during this audit?
Y _____ N _____

NCI DARF COMPLETELY AND CORRECTLY FILLED OUT

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- Maintain accurate records of the disposition of all CTEP supplied agents using NCI DARFs.
- Agents supplied by the PMB for NCI-sponsored protocols should be shipped from PMB directly to the investigator's primary institution or office.
- In situations where two or more institutions are operating as a "centralized research base", a centralized pharmacy service can provide pharmacy services (such as agent storage, preparation and accountability) for investigators in the local community, if the investigators designate that pharmacy service as their shipping designee on their FDA form 1572 submitted to PMB. The centralized pharmacy is then permitted to **deliver (not re-ship)** CTEP supplied investigational agents to the investigator's offices, clinics, or other institutions.
- Agents may be dispensed, delivered, and accounted for at the treatment site in response to an individual patient's treatment order or a prescription for a single dose or treatment cycle. In this situation, there is no need for satellite accountability records.
- If the physician's office, clinic, or other institution receives a multiple day supply of CTEP supplied investigational agents, satellite accountability records must be maintained for each satellite location and copies must be available for review by site auditors.

NONCOMPLIANCE

- Inability to track the receipt, use and disposition of DCTD supplied investigational agents.
- NCI DARF not maintained.
- Inability to track agent because of omissions.
- Electronic DARFs do not contain all information required on NCI DARF.
- Paper printout is not identical to the NCI DARF.
- Incorrect agent, dose, route of administration, or dates documented on DARF.
- Registered patients who have received IND agents are not recorded on DARF.
- Systematic incorrect entries on the DARF.
- NCI DARF not kept on timely basis.
- There are erasures or "whiteouts".
- Corrections are not lined out and initialed.
- Agent has been transferred to an investigator who is not registered with PMB, DCTD, NCI.
- No Satellite NCI DARF.
- CTEP supplied investigational agents are repackaged and/or reshipped to other investigators or locations by mail or express carrier.

PROTOCOL AND DRUG SPECIFIC

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- Agents received from PMB, DCTD are used only for patients entered onto an approved DCTD-sponsored protocol.
- Each agent accounted for separately by protocol.
- An agent used for more than one protocol has a separate DARF for each protocol.
- Multi-agent protocols have a separate DARF for each agent.
- Separate accountability forms maintained for each different strength or dosage form of a particular agent.

NONCOMPLIANCE

- Patients identified on DARF are not registered patients.
- Substitution with any non-DCTD supplied agents, including commercial agents.
- Agents supplied for clinical trials used for pre-clinical or laboratory studies without written approval of PMB.
- Lack of source documentation to verify agent supplies distributed to investigators or administered to patients.
- Each agent not accounted for separately by protocol.
- One DARF used for more than one protocol.
- One DARF for a multi-agent protocol.
- One DARF used for multiple strengths or dosage forms of an agent.

SATELLITE RECORDS

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- DARF used at each location where agents are stored and/or dispensed e.g., main pharmacy, satellite pharmacy, physician's office, or other dispensing areas.

NONCOMPLIANCE

- Satellite and control records are not accurately maintained.
- Satellite and control records do not agree.

NCI DARFs KEPT AS PRIMARY TRANSACTION RECORD

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- Agent order receipts (Shipment Record of Clinical Drug Request, NIH 986-1) retained and available for review.
- Documentation on DARF of other agent transaction: agent returns, broken vials, etc.
- Inter-institutional transfer of DCTD investigational agents is approved or authorized by PMB.
- Balance on DARF matches supply.

NONCOMPLIANCE

- Agent order receipts (Shipment Record of Clinical Drug Request, NIH 986-1) not retained or not available for review.
- Lack of documentation of other agent transactions.
- Agents have been borrowed.
- Transfer Investigational Drug Form (NIH 2564) not used when transferring agent.
- Quantities not accounted for; shelf counts and inventories do not match.
- No faxed documentation from PMB of approval for transfer of agent.
- No satellite NCI DARF.

RETURN OF DRUG TO NCI

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- Return to DCTD agents (a) that are outdated; and (b) that are damaged or unfit for use.
- For studies that are completed or discontinued, return DCTD agents to the NCI or appropriately transfer to another NCI protocol.

NONCOMPLIANCE

- DCTD agent not returned to NCI or transferred to an appropriate NCI protocol.
- Not using the transfer form when transferring a DCTD supplied agent to an approved NCI protocol.

STORAGE

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- Each investigational agent stored separately by protocol.
- An agent used for more than one protocol kept in separate physical storage for each protocol.
- Agent stored under proper conditions (refrigerator, freezer, etc.) with validation documentation.

NONCOMPLIANCE

- IND not stored separately by protocol.
- Agents used for more than one protocol combined in storage.
- Agent not stored under proper conditions.

SECURITY

Compliant _____ Noncompliant _____ NR _____

COMPLIANCE

- Agent stored in a secure location accessible to only authorized personnel.

NONCOMPLIANCE

- Agent stored in insecure dispensing area.

Comments:

_____

_____

_____

Accountability of Investigational Agents and Pharmacy Operations Assessment

_____ Acceptable

_____ Acceptable Needs Follow-up

_____ Unacceptable

_____ No Assessment Required

Reaudit required: No _____ Yes _____ Within _____ months

III. REVIEW OF PATIENT CASE RECORDS

Protocol	Patient #	Category	Deficiencies (None, Major, Lesser, NR)	Comments
		Informed Consent Eligibility Treatment Disease Outcome/Response Toxicity General Data Quality		
		Informed Consent Eligibility Treatment Disease Outcome/Response Toxicity General Data Quality		
		Informed Consent Eligibility Treatment Disease Outcome/Response Toxicity General Data Quality		

Review of Patient Case Records Assessment

_____ Acceptable

_____ Acceptable Needs Follow-up

_____ Unacceptable

Reaudit: No _____ Yes _____ Within _____ months

General Comments:

Exit Interview: