Clinical Trials Monitoring Branch – Audit Checklist

Audit Date:	**NCI Code:**	**Institution:**

Institution Staff	**Title**

Audit Team	Institution/Group Affiliation

IRB Review (Table A)

	IRB Deficiency Type	Comments
Major	Protocol never approved by IRB	
	Initial IRB approval documentation missing	
	Initial approval by expedited review	
	Expedited reapproval for situations other than approved exceptions	
	Registration and/or treatment of patient prior to full IRB approval	
	Reapproval delayed greater than 30 days but less than one year	
	Registration of patient on protocol during a period of delayed reapproval	
	Missing reapproval	
	Expired reapproval	
	Internal reportable adverse event reported late or not reported to IRB	
	Lack of documentation of full IRB approval of protocol amendment that affects more than minimal risk and/or IRB approval is >90 days after Group's notification	
	Failure to submit or submitted after 90 days, any external safety report to the IRB for unexpected >= grade 3 event with an attribution of possible, probable or definite, unless the local IRB policy does not mandate reporting of external safety reports	
Lesser	Reapproval delayed less than 30 days	
	Delayed reapprovals for protocols closed to accrual for which all patients have completed therapy	
	Other (describe)	

Informed Consent Content (ICC) Review (Table B)

ICC Deficiency Type		Comments
Elements Required by Federal Regulations	Involves research, purposes, duration of participation, description of procedures, identification experimental procedures	
	Description of risks or discomforts	
	Description of any benefits to subject or others	
	Disclosure of alternative procedures or treatments	
	Description of the extent of confidentiality of records	
	Explanation regarding compensation and/or whether treatments are available if injury occurs	
	Was there an 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	
	Participation is voluntary; refusal to participate involves no penalty; subject may discontinue participation at any time	
Additional Elements Required by Federal Regulation when appropriate	Unforeseeable risks to subject, embryo, or fetus	
	Circumstances in which subject’s participation may be terminated by investigator without subject’s consent	
	Additional costs to subject which may result from participation in research	
	Consequences of subject withdrawal and procedures for orderly termination of participation by subject	
	Statement that new findings which may relate to subject’s willingness to continue participation will be provided to subject	
	Disclosure of approximate number of participants	
	Statement that a copy of the consent will be given to participant	
	Other (describe)	

Pharmacy Review (Table C)
Accountability of Investigational Agents and Pharmacy Operations Review

(see NCI/CTMB Guidelines under Section 5.3.1 for pharmacy 'compliance' listing)

NCI DARFs completely and correctly filled out (non-compliance)	Comments
Inability to track receipt, use, and disposition of DCTD/DCP supplied investigational agents	
NCI DARF not maintained	
Inability to track the 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	
CTEP supplied investigational agents are repackaged and/or reshipped to other investigators/locations by mail or express carrier	

NCI DARFs were protocol and drug specific (non-compliance)	Comments
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	
DARF incorrectly used (single DARF used for multiple patients for double blinded study; multiple dose vials recorded for one patient instead of multiple patients, or multiple doses recorded on a single line of the DARF, etc.)	

Satellite records accounted for (non-compliance)	Comments
Satellite and control records are not accurately maintained	
Satellite and control records do not agree	

NCI DARFs kept as primary transaction record (non-compliance)	Comments
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 (non-compliance)	Comments
DCTD/DCP agent not returned to NCI or transferred to an appropriate NCI protocol	
Not using the transfer form when transferring a DCTD/DCP supplied agent to an approved NCI protocol	
DCTD/DCP agents are not returned when all patients are in follow-up	
Patient return of IND supplied agents are recorded on the DARF for non-double blinded studies	

Agent(s) stored by protocol (non-compliance)	Comments
IND not stored separately by protocol	
Agents used for more than one protocol combined in storage	
Agents not stored under proper conditions	

Adequate Security (non-compliance)	Comments
Agent stored in insecure dispensing area	
Unauthorized people having access to a secure area without supervision	

Patient Case Deficiency Review (Table D)

Informed Consent (majors)	Comments
Consent form missing	
Consent form not signed and dated by patient	
Consent form signed after patient started on treatment	
Consent form does not contain all required signatures	
Consent form used was not current IRB-approved version at time of patient registration	
Consent form was not protocol specific; consent form does not include updates or information required by IRB	
Reconsent not obtained as required	
Other (describe)	
Eligibility (majors)	**Comments**
Review of documentation available at the time of audit confirms patient did not meet all eligibility criteria as specified in the protocol	
Documentation missing; unable to confirm eligibility	
Other (describe)	
Treatment (majors)	**Comments**
Incorrect agent/treatment used	
Additional agent/treatments used which is not permitted by protocol	
Dose deviation, modification, or calculations incorrect (error greater than +/- 10%)	
Dose modification unjustified	
Treatment doses incorrectly administered, calculated, or documented	
Unjustified delays in treatments	
Other (describe)	

Patient Case Deficiency Review (Table D)

Disease Outcome/Response (majors)	Comments
Inaccurate documentation of initial sites of involvement	
Tumor measurements/evaluation of status or disease not performed according to protocol	
Protocol directed response criteria not followed	
Claimed response (PR, CR, etc) cannot be verified	
Failure to detect cancer (as in a prevention study) or failure to identify cancer progression	
Other (describe)	
Adverse Event (majors)	**Comments**
Grades, type, or dates/duration of serious adverse events inaccurately recorded	
Adverse events cannot be substantiated	
Follow-up studies necessary to assess adverse events not performed	
Failure to report an adverse event that would require filling an Adverse Event Reaction (AER)	
Recurrent under- or over-reporting of adverse events	
Other (describe)	
General Data Management Quality (majors)	**Comments**
Recurrent missing documentation (e.g., charts)	
Protocol specified laboratory tests not reported or not documented	
Protocol specified diagnostic studies not reported or not documented	
Frequent data inaccuracies	
Errors in submitted data	
Delinquent data submission (> 6 months delinquency is a major deficiency; 3-6 months is a lesser deficiency)	
Other (describe)	