



Regulatory Documentation Audit Worksheet

IRB of Record: **NCI CIRB** or **Local IRB** (circle one) Audit Date: _____

CTEP Site Code: _____ Protocol #: _____ # of Pt Cases Audited: _____

IRB Review – Overall Comments:

Informed Consent Content (ICC) Review – Overall Comments:

Delegation of Tasks Log (DTL) Review – Overall Comments:

IRB – List of Deficiencies

Protocol #: _____

CIRB Review			
Critical Deficiency	Yes	No	Comments
Any finding identified before or during an audit that is suspected to be fraudulent activity	[]	[]	
Major Deficiencies	Yes	No	Comments
Unanticipated problems, Serious Non-Compliance and/or Continuing Non-Compliance (per OHRP) problems not reported	[]	[]	
Institution enrolls under an incorrect CTEP site code and the institution or institution CTEP site code is not covered by the CIRB	[]	[]	
Other (explain)	[]	[]	
Lesser Deficiencies	Yes	No	Comments
Copy of CIRB approval letter/study worksheet is not available or accessible at the time of the audit	[]	[]	
Other (explain)	[]	[]	
Local IRB Review			
Critical Deficiency	Yes	No	Comments
Any finding identified before or during an audit that is suspected to be fraudulent activity	[]	[]	
Major Deficiencies	Yes	No	Comments
Initial approval by expedited review instead of full-board 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 calendar days, but less than one year	[]	[]	

IRB – List of Deficiencies (cont...)

Protocol #: _____

Pt Case #: _____

Local IRB Review (cont...)			
Registration of patient on protocol during a period of delayed reapproval or during a temporary suspension (i.e., Request for Rapid Amendment)	[]	[]	
Missing reapproval	[]	[]	
Expired reapproval	[]	[]	
Internal reportable adverse events reported late or not reported to the IRB	[]	[]	
Lack of documentation of IRB approval of a protocol amendment that affects more than minimal risk or IRB approval is greater than 90 calendar 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	[]	[]	
Failure to submit or submitted after 90 calendar days, any reportable external safety report to the IRB that is considered an unanticipated problem as defined by OHRP, unless there is a local IRB policy that does not mandate reporting of external safety reports	[]	[]	
Other (explain)	[]	[]	
Lesser Deficiencies	Yes	No	Comments
Protocol reapproval delayed 30 calendar days or less	[]	[]	
Delayed reapproval for protocol closed to accrual for which all study participants have completed therapy	[]	[]	
Amendment/Investigator Brochure editorial revision or administrative in nature or other Network Group/NCORP Research Base specific document not submitted or not submitted timely to the local IRB	[]	[]	
Other (explain)	[]	[]	

Informed Consent Content (ICC) – List of Deficiencies

Protocol #: _____

Pt Case #: _____

ICC Review			
Critical Deficiency	Yes	No	Comments
Any finding identified before or during an audit that is suspected to be fraudulent activity	[]	[]	
Major Deficiencies	Yes	No	Comments
Missing any of the following statements or language specific to the elements required per the federal regulations:	[]	[]	
a. Involves research, purposes; duration of participation; description of procedures; identification of experimental procedures	[]	[]	
b. Description of <u>foreseeable</u> risks or discomforts	[]	[]	
c. Description of any benefits to subjects or others	[]	[]	
d. Disclosure of alternative procedures or treatments	[]	[]	
e. Description of the extent of confidentiality of records	[]	[]	
f. Explanation regarding compensation and/or whether treatments are available if injury occurs, including who to contact if injury occurs	[]	[]	
g. Explanation of whom to contact for answers to pertinent questions about the research and whom to contact for questions related to research subject's rights	[]	[]	
h. Statement that participation is voluntary; refusal to participate involves no penalty or loss of benefits; subject may discontinue participation at any time	[]	[]	
i. Unforeseeable risks to subject, embryo or fetus	[]	[]	

ICC – List of Deficiencies (cont...)**Protocol #:** _____**Pt Case #:** _____

j. Statement that circumstances in which subject's participation may be terminated by the investigator without subject consent	<input type="checkbox"/>	<input type="checkbox"/>	
k. Statement of additional costs to subject that may result from participation in the study	<input type="checkbox"/>	<input type="checkbox"/>	
l. Statement of consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	<input type="checkbox"/>	<input type="checkbox"/>	
m. Statement that significant new findings which may be related to subject's willingness to continue participation will be provided to subject	<input type="checkbox"/>	<input type="checkbox"/>	
n. Disclosure of approximate number of subjects involved in the study	<input type="checkbox"/>	<input type="checkbox"/>	
o. Statement: "A description of this clinical trial will be available on www.clinicaltrials.gov , as required by US 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"	<input type="checkbox"/>	<input type="checkbox"/>	
Statement that a copy of the consent form will be given to the subject			
Failure to revise the informed consent document in response to an NCI Action Letter regarding risks	<input type="checkbox"/>	<input type="checkbox"/>	
Significant or substantial changes to the consent form document deviating from the CIRB-approved boilerplate (other than local context) not approved by the CIRB	<input type="checkbox"/>	<input type="checkbox"/>	
Consent form document contains changes not approved by the local IRB, including changes to questions that do not match the model consent form	<input type="checkbox"/>	<input type="checkbox"/>	

ICC – List of Deficiencies (cont...)**Protocol #:** _____**Pt Case #:** _____

Multiple cumulative effect of lesser deficiencies for a given consent form	<input type="checkbox"/>	<input type="checkbox"/>	
Other (explain)	<input type="checkbox"/>	<input type="checkbox"/>	
Lesser Deficiencies	Yes	No	Comments
Failure to have the informed consent document (after CIRB amendment approval) locally implemented within 30 calendar days of notification (posted on the CTSU website)	<input type="checkbox"/>	<input type="checkbox"/>	
Language/text is missing or added that is administrative or editorial in nature (e.g., rephrasing a sentence/section to add clarity, reformatting the document and/or changes made related to contact information are examples of an editorial or administrative change)	<input type="checkbox"/>	<input type="checkbox"/>	
IRB approved informed consent document with incorrect version date	<input type="checkbox"/>	<input type="checkbox"/>	
Other (explain)	<input type="checkbox"/>	<input type="checkbox"/>	

Delegation of Tasks Log (DTL) – List of Deficiencies**Protocol #:** _____**Pt Case #:** _____

Delegation of Tasks (DTL) Review			
Critical Deficiency	Yes	No	Comments
Any finding identified before or during an audit that is suspected to be fraudulent activity	[]	[]	
Major Deficiencies	Yes	No	Comments
Performing tasks not assigned to individual	[]	[]	
Failure to keep DTL current	[]	[]	
Individual performing study-related activities not listed on DTL	[]	[]	
Other (explain)	[]	[]	
Lesser Deficiency	Yes	No	Comments
Other (explain)	[]	[]	