Clinical Trials Monitoring Branch (CTMB)
Cancer Therapy Evaluation Program (CTEP)
Division of Cancer Treatment and Diagnosis (DCTD)

Regulatory Documentation Review Worksheet

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

CTEP Site Code: _____ **Protocol #: _____** **# of Pt Cases Reviewed:_____**

IRB Review – Overall Comments:

Informed Consent Content (ICC) Review – Overall Comments:

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

IRB – List of Deficiencies

Protocol #: _____
Pt Case #: _____

CIRB Review			
Critical Defiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	[ ]	[ ]	
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 review	[ ]	[ ]	
Other (explain)	[ ]	[ ]	
Local IRB Review			
Critical Deficiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	[ ]	[ ]	
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 (or 120 calendar days for sites outside of the U.S.) 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 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 the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	[ ]	[ ]	
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 foreseeable 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	[ ]	[ ]	
k. Statement of additional costs to subject that may result from participation in the study	[ ]	[ ]	
l. Statement of consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	[ ]	[ ]	
m. Statement that significant new findings which may be related to subject's willingness to continue participation will be provided to subject	[ ]	[ ]	
n. Disclosure of approximate number of subjects involved in the study	[ ]	[ ]	
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"	[ ]	[ ]	
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	[ ]	[ ]	
Significant or substantial changes to the consent form document deviating from the CIRB-approved boilerplate (other than local context) not approved by the CIRB	[ ]	[ ]	
Consent form document contains changes not approved by the IRB of record, including changes to questions that do not match the model consent form	[ ]	[ ]	

ICC – List of Deficiencies (cont…)

Protocol #: _____
Pt Case #: _____

Multiple cumulative effect of lesser deficiencies for a given consent form	[ ]	[ ]	
Other (explain)	[ ]	[ ]	
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)	[ ]	[ ]	
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)	[ ]	[ ]	
IRB approved informed consent document with incorrect version date	[ ]	[ ]	
Other (explain)	[ ]	[ ]	

Delegation of Tasks Log (DTL) – List of Deficiencies

Protocol #: _____

Pt Case #: _____

Delegation of Tasks (DTL) Review			
Critical Defiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	**[ ]**	**[ ]**	
Major Deficiencies	**Yes**	**No**	**Comments**
Performing tasks not assigned to individual	[ ]	[ ]	
Failure to sign DTL annually	[ ]	[ ]	
Individual performing study-related activities not listed on DTL	[ ]	[ ]	
Other (explain)	[ ]	[ ]	
Lesser Deficiency	**Yes**	**No**	**Comments**
Other (explain)	[ ]	[ ]	