IRB Review

Protocol #: _____ CTEP Site Code: _____ # of Patient(s) Audited: ____

IRB of Record: NCI CIRB or Local IRB (circle one)

Overall Comments for IRB:

Overall IRB Deficiency Rating [ ] Major [ ] Lesser [ ] OK

Overall Comments for ICC:

Overall ICC Deficiency Rating [ ] Major [ ] Lesser [ ] OK

IRB Deficiencies **Protocol Number: _____**

Major Deficiency	Yes	No	Comments
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 or during a temporary suspension (ie, Request for Rapid Amendment)	[ ]	[ ]	
Missing reapproval	[ ]	[ ]	
Expired reapproval	[ ]	[ ]	

Major Deficiency		Yes	No	Comments
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 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 days, any reportable external safety report to the IRB that is considered an unanticipated problem as defined by OHRP		[ ]	[ ]	
Lesser	Protocol reapproval delayed 30 days or less	[ ]	[ ]	
	Delayed reapproval for protocol closed to accrual for which all patients/study participants have completed therapy	[ ]	[ ]	
Other deficiencies found for IRB (Note if major or lesser)		[ ]	[ ]	

IRB/ICC AUDIT WORKSHEET

ICC Deficiencies **Protocol Number: _____**

Deficiency	Yes	No	Comments
Involves research: purposes; duration of participation; description of procedures; identification of 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	[ ]	[ ]	
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	[ ]	[ ]	
Unforeseeable risks to subject, embryo or fetus	[ ]	[ ]	

IRB/ICC AUDIT WORKSHEET

Deficiency	Yes	No	Comments
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 stating: "A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. 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 will be given to study participant	[ ]	[ ]	
Other deficiencies found for ICC (Note if major or lesser)	[ ]	[ ]	