ensuring the initial and ongoing qualifications of investigators and research staff
monitoring protocol compliance
maintaining compliance with state, local or institutional requirements related to the protection of human subjects
providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research
investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance.

USA investigators planning to conduct a study for which NCI CIRB serves as the IRB of record must receive USA IRB preliminary review and approval to ensure compliance with institutional requirements that are ___ evaluated by the CIRB's local subcommittee. The USA IRB review will be initiated by the IRB staff.

When an investigator wishes to open a Cooperative Group clinical trial the following steps must be followed:

1.1 Create a New Project in IRBNet
1.2

Currently, there is no USA IRB language to be inserted into a CIRB consent or assent form. However, specific HIPAA and GINA language is required as a separate stand-alone document that is presented to the subject during the consent process. The USA IRB will review, approve and stamp these documents.

3.1 After the USA IRB application and required documentation is submitted in IRBNet, it is reviewed by the USA IRB Office to ensure that:

- Institutional requirements for reliance are met, such as training and absence of conflict of interest issues.
  Separate stand-alone HIPAA and GINA documents are within institutional standards.

3.2 If revisions are needed, the IRBNet package will be unlocked with instructions to complete/revise submission. NOTE: “Mark Revisions Complete” must be selected to notify the IRB that the project is ready for review.

3.3 After all revisions are complete and the IRB is notified, the study team will receive IRBNet notification of the USA IRB Acknowledgment Letter. The board action document is located in IRBNet under “Reviews” when the study title is selected stating the study is eligible for reliance on the 1m003>5 Td [h( )-3 (Le)[h( )-RBji19A>BDC

4.4.2 Both an Annual Principal Investigator Worksheet and a Study-Specific Principal Investigator Worksheet must be approved by the NCI CIRB before a study may be conducted.

Research Involving Children: The NCI CIRB will make the determination whether of the child is required. Procedures for obtaining and documenting assent should follow the USA IRB policies and procedures outlined in *SOP 703: Informed* authorization to review protocols.

1.8 Notify the local institution of any CIRB policy decisions or regulatory matters that might affect the institution's reliance on CIRB reviews or performance of the research at the local institution.

Study holds or suspensions from NCI CIRB or Sponsor that are not built into the study design (e.g.: interim analysis or enrollment complete need not be reported)
Study terminations from NCI CIRB or sponsor
Any death of a participant outside of death as a result of natural disease progression
Study closure

2.8 As appropriate, add local restrictions, stipulations, or substitutions to CIRB approved informed consents. Deletion of CIRB approved requirements in the protocol and Informed Consent Form is not allowed, and substantive changes that affect the meaning of CIRB approved requirements are not allowed.

3.1. In collaboration with the Office of Research Compliance and Assurance, initiate and update the institution's Annual Signatory Institution Worksheet approved by NCI CIRB.

3.2. Signatory Institution Primary Contact (IRB Office)

3.3.

Prisoners.

Research conducted under the exception to the requirement for informed consent for emergency research outlined in FD 21 CFR 50.24

Reports of emergency use of a test article as outlined in 21 CFR 56.102(d), 56.104(c) and 312.36 or the use of a test article without consent outlined in 21 CFR 50.23

HIPAA authorization language or requests for HIPAA waivers

Transnational research

21 CFR 56.113; 45 CFR 46.113

IRB External Review Request Form (located in IRBNet)
SOP 703: Informed Consent: Research Involving Children
SOP 903: Research Involving Prisoners

National Cancer Institute Central Institutional Review Board

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Office of Research Compliance and Assurance