CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

TITLE: 3.2: Reviews Requiring Special Consideration: NCI STUDIES	
Original Date: January 2006	**Date of Last Revision:** 6-13, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

Researchers wishing to open adult or pediatric cooperative group oncology trials approved by the National Cancer Institute Central Institutional Review Board (NCI CIRB) may submit the appropriate documents to the Carilion Institutional Review Board (IRB). If the Carilion IRB accepts the NCI CIRB review, the NCI CIRB will become the IRB of record. This guideline describes the process of interaction between the Carilion IRB and the NCI CIRB.

General Description:

NCI CIRB Responsibilities

- Maintain an NCI CIRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
  (a) Post the roster of NCI CIRB membership on the public side of the NCI CIRB website;
- Conduct initial, amendment, and continuing review of studies as well as review of any other study-specific documents submitted by the Study Chair to the NCI CIRB;
- Conduct review of local context considerations:
  (a) as outlined in the following Worksheets: the Annual Signatory Institution Worksheet About Local Context for NCI CIRB Review, the Annual Principal Investigator Worksheet About Local Context, and the Study-Specific Worksheet About Local Context;
- Conduct review of potential unanticipated problems and/or serious or continuing noncompliance when the Signatory Institution or other entity reports an incident, experience, or outcome to the CIRB. This review includes the following step:
  a) report any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA, and the NCI Signatory Official;
- Conduct review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or equivalent monitoring body;
- Post all study-specific documents related to CIRB reviews to the restricted access side of the CIRB website;
  a) Notify research staff and institutional designees of all CIRB actions, per written procedures, via institution-specific correspondence, broadcast emails, and access to the restricted area of the CIRB website;
- Notify the Signatory Institution immediately if there is ever a suspension or restriction of the CIRB's authorization to review a study; and
- Post the NCI CIRB Standard Operating Procedures on the public side of the CIRB website.

Carilion Clinic Responsibilities

- Comply with the NCI CIRB's requirements and directives;
- Report to the NCI CIRB the names of any Component or Affiliate Institutions that rely on the Signatory Institution's IRB.
- Ensure the safe and appropriate performance of the research at the Signatory Institution and at all Components and Affiliates. This includes, but is not limited to:
  a) ensuring the initial and ongoing qualifications of investigators and research staff;
  b) overseeing the conduct of the research including the authority to observe any aspect of the research process including observing the consent process.
  c) monitoring protocol compliance;
  d) maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
  e) providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
  f) 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. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the institution must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences;
- Provide updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is no longer the responsible party for a study under the purview of the NCI CIRB;
- Notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review;
- Complete and submit the Annual Institution Worksheet About Local Context, the Annual Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation;
- Decide on a study-by-study basis whether to open the study through the NCI CIRB or to conduct its own local IRB full Board review. Indicate the decision to open a study through the NCI CIRB by submitting a Study-Specific Worksheet About Local Context;
- In the local consent form:
  a) incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form;
  b) make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language;
  c) obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
  d) obtain NCI CIRB approval of translations of the consent form prior to implementation;
- Maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy; and
- Identify an appropriate IRB to conduct Full Board review of any study where it is anticipated or becomes necessary to enroll prisoners.

Procedure:

New Approval

- Research team will obtain the applicable study documents from the NCI CIRB website and documents will be reviewed by the Carilion Clinic (CC) Principal Investigator (PI).
- Research Team will submit to CC IRB using the electronic submission system PRIS3M:
    - Request to Rely application
    - Carilion Clinic HIPAA Authorization
    - All study related materials
- Research team will add local template language to the consent and submit to NCI CIRB
    - Contact Information for Principal Investigator
    - Contact Phone # for CC IRB for Subjects' Rights questions.
    - Conflict of Interest Language, if there is a financial conflict
- Carilion IRB staff will verify that all training and documentation are in order & notify PI/coordinator via email that study can be submitted to NCI IRB.
- The Carilion Clinic PI will access NCI CIRB website and request the study be opened at Carilion Clinic.
- The Carilion Clinic PI will notify CC IRB when the study is approved by NCI CIRB.
- The approval will be communicated to the IRB members.

Continuations

- Research Team will submit Continuing Review to NCI CIRB.
- Continuing Reviews will be completed and approved by the NCI CIRB.
- When the PI/study coordinator has received a continuation approval from the NCI CIRB he/she will submit the NCI CIRB continuation approval letter to the CC IRB.

Amendments

- Amendments and Revisions reviews will be completed by the NCI CIRB.
- Documentation that should be submitted to the CC IRB:
    - Local research team personnel changes.
    - Notification of permanent closure to enrollment.
    - Change in the Recruitment Plan that would require a HIPAA Waiver.
    - Change in Financial Conflict of Interest

Protocol Violations and Deviations

The PI is responsible for submitting local protocol violations, deviations, and individual adverse event reports to the Carilion IRB.

Unanticipated Problems/Adverse Events

Unanticipated problems/serious adverse events that occur locally and that meet reporting criteria are required to be submitted to the Carilion IRB. Adverse events will be reviewed according to Carilion IRB guidelines. NCI CIRB will also review individual adverse event reports for studies without a Data Safety Monitoring Board or equivalent monitoring body.

Documentation

All approvals and correspondence with the NCI CIRB and local research team will be stored in the IRB electronic submission system and/or the secure password protected HRPO shared drive.