



CAMC Institute – Research and Grants Administration  
CAMC/WVU-Charleston Division Institutional Scientific Review Board

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Policy Title	National Cancer Institute Central Institutional Review Board Use
Version	2
Version Date	May 25, 2010
Effective Date	June 1, 2010

**Scope:**

This policy is to establish guidelines for acceptance of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) and Pediatric Central Institutional Review Board (PCIRB) approved protocols in accordance with DHHS regulations at 45CFR46.1114.

The CAMC/WVU-Charleston Division Institutional Review Board (FWA 00002709) has designated the National Cancer Institute (NCI) Central Institutional Review Boards (NCI CIRB #1 (adult) IRB00000781 and NCI CIRB #2 (pediatric) IRB00004296 as IRBs of record for Pilot Studies, Phase II Cancer Cooperative Group trials as a participant of the CIRB initiative.

**CFRs:**

45CFR46.1114; 45CFR46

**Facilitated Local Review:**

For the purposes of this policy, facilitated local review refers to the process for local CAMC/WVU-Charleston Division IRB review of NCI CIRB/PCIRB protocols.

**Division of Responsibilities:**

The division of responsibilities between the NCI CIRB and NCI Pediatric CIRB and the CAMC/WVU-Charleston Division IRB will follow the Division of Responsibilities outlined by the NCI CIRB and the NCI Pediatric CIRB policies and the IRB Authorization Agreement.

**The Responsibilities of the NCI CIRB/PCIRB are to:**

- Maintain and make accessible to CAMC/WVU-Charleston Division IRB, the CIRB application, protocol review letters to principal investigators, approvals and disapprovals, and minutes of the CIRB/PCIRB meetings; carry out continuing reviews, reviews of serious adverse events, reviews of protocol amendments, and reviews of any other submitted documentation;
- Maintain current registration of its IRBs with OHRP;
- Maintain a Board membership that satisfies the requirements 45 CFR 46 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of each protocol

**The Responsibility of the CAMC/WVU-Charleston Division IRB is to:**

- Ensure the safe and ethical performance of the research at CAMC/WVU-Charleston Division Ensure the investigators and staff that conduct the trial are appropriately qualified and meet institutional standards for eligibility to conduct research;
- Notify the CIRB and/or the Pediatric CIRB immediately if there is a suspension or restriction of a local investigator or the IRB's authorization to review protocols;
- If the CAMC/WVU-Charleston Division IRB accepts the CIRB/PCIRB approval of a protocol, it will record and maintain documentation of the decision and evidence that it has received and considered all CIRB/PCIRB material relevant to the protocol;
- Accept CIRB/PCIRB approval of continuing reviews, consent form and protocol amendments, unless CAMC/WVU-Charleston Division IRB review is requested by a local investigator;
- Maintain an OHRP approved Assurance for Human Subjects Research;
- Maintain an IRB whose membership satisfies the requirements of 45CFR46;
- Maintain compliance with any additional state, local or institutional requirements related to the protection of human subjects

**Procedure:**

**Principal Investigator responsibilities for local Facilitated Review:**

For each submission, the following must be submitted to the Office of Research and Grants Administration per the Submission Procedure.

**New Study Submission:**

- Complete and submit local application for review, including all required institutional signatures
- Provide the most recent CIRB or Pediatric CIRB approval letter
- Provide the most recent CIRB or Pediatric CIRB approved consent and assent forms with local language, HIPAA Authorization and contact requirements

Revision:

- Provide the CIRB or Pediatric CIRB approval letter for the revision to be considered
- If appropriate, provide the most recent CIRB and Pediatric CIRB approved consent and assent forms with local language, HIPAA Authorization and contact requirements
- Provide the local current Revision Tracking Log

Submission of Information:

- Provide the CIRB or Pediatric CIRB approval letter for the information to be considered
- Provide the local current Revision Tracking Log

Continuing Renewal:

- Provide the CIRB or Pediatric CIRB approval letter for the renewal to be considered
- Provide a copy of the recent Data Safety Monitoring Board letter and/or report
- Provide the local current Revision Tracking Log
- Provide the local current Adverse Event Tracking Log
- Provide the local current Deviation Log

Internal Adverse Event/Death:

- Complete and submit the local Adverse Event Report form for serious, unexpected and/or ongoing local events
- Provide supporting medical documents (records, death certificate, etc)
- Provide the most recent CIRB or Pediatric CIRB approved consent and assent forms with local language, HIPAA Authorization and contact requirements
- Provide the local current Adverse Event Tracking Log

**IRB Responsibilities for local Facilitated Review:**

All CIRB and Pediatric CIRB paperwork submitted for review to the CAMC/WVU-Charleston Division IRB will receive an administrative review by a staff member of the Office of Research and Grants Administration. If questions arise during any review regarding content, safety, ethics, etc one Board member will be contacted to conduct a review of the submission.

- Review all submitted paperwork to ensure local requirements are met
- Review paperwork available on the CIRB website
- Complete the online Facilitated Review Acceptance Form on the CIRB website
- Create a study file to include all submitted and review study information