16.0 SUBMITTING A COOPERATIVE GROUP PEDIATRIC OR ADULT PROTOCOL to THE NATIONAL CANCER INSTITUTE (NCI)

16.1 OBJECTIVE

To outline the procedures for submitting a cooperative group pediatric or adult protocol to the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) application for facilitated Howard University (HU) IRB review.

16.2 GENERAL DESCRIPTION

In accordance with NCI CIRB regulations and HU policies and procedures, data collection of NCI cooperative group sponsored pediatric or adult research must be reviewed by the NCI CIRB initially. It is the responsibility of each investigator that does NCI cooperative group sponsored pediatric or adult research to seek such review of any research study involving pediatric or adult human subjects prior to initiation of the project.

16.3 RESPONSIBILITY

Execution of SOPP: IRB Chair, IRB Member, IRB Facilitated Reviewer, Principal Investigator (PI)/Study Personnel, Office of Research Regulatory Compliance (ORRC) Staff, ORRC Director, ORRC Research Compliance Officer

16.4 PROCEDURES

16.4.1 Submission for Pediatric Protocols

- The PI notifies study coordinator of the NCI CIRB approved study he/she would like to conduct. The PI/study personnel downloads all CIRB documents (protocol, consent form, CIRB application) from the “Members” area on the CIRB website (www.ncicirb.org) and completes and submits the required CIRB application documents to the NCI CIRB.

- The PI submits the NCI CIRB protocol and supporting documentation to the ORRC for review by the HU IRB.

- The protocol title as submitted to the HU IRB must contain the word “NCI-CIRB” at the beginning of the title. Upon receipt of a copy of the NCI CIRB application document, ORRC staff assigns the document an IRB protocol number.

- ORRC staff schedules the IRB application for review and the IRB proceeds with review in accord with this IRB SOP independent of the PRC review.

16.4.2 Submission for Adult Protocols

- The PI notifies the applicable managing cooperative group of the NCI CIRB approved study he/she would like to "open". The PI/study personnel downloads all CIRB documents (protocol, consent form, CIRB application) from the "Members" area on the CIRB website) and completes and submits the required CIRB application documents to the NCI CIRB.

- The protocol title as submitted to the HU IRB must contain the word "NCI-CIRB" at the beginning of the title. Upon receipt of a copy of the NCI CIRB application document, ORRC staff assigns the document an IRB protocol number.

- ORRC staff forwards the IRB application for review and the IRB proceeds with review in accord with this IRB SOPP.

16.4.3 Facilitated IRB Review and Local Modification of the Application

- The facilitated reviewer, who is a voting IRB member, completes a facilitated review and determines whether there are local concerns that need to be addressed and whether to accept CIRB review. The NCI CIRB facilitated reviewer is provided a copy of CIRB review paperwork from the CIRB website (including IRB minutes, approval letter, scientific and non-scientific reviews) once the NCI CIRB review is complete.

- The facilitated reviewer may propose/approve minor additions to the protocol or word substitutions in the informed consent document to facilitate better comprehension by the local population and add state and local law and institutional requirements or IRB policies but may not delete or contradict any protocol contents in order for the NCI CIRB to be the IRB of record.

- The PI works with the ORRC staff to modify the informed consent form to meet the HU facilitate reviewer's request for minor modifications (if any) and informed consent form template and applicable HIPAA form(s) according to the HU HIPAA template.

- ORRC staff screens the application to determine if it is complete (e.g., includes the modifications to HU specific language in the informed consent form and has appropriate signatures). If it is not complete, ORRC staff returns the application to the investigator or in cases where only a few minor items are missing, ORRC staff calls or writes the investigator to request the missing items. ORRC staff also screen the CIRB application to ensure that the PI has completed applicable HIPAA forms.

- ORRC staff ensures that all study personnel have completed the mandatory HU human subject protection training. If the PI has not completed training, ORRC staff notifies him/her in writing and request the PI to send the appropriate certifications. The IRB does not issue approval until the ORRC receives the training certifications. A PI may submit a request for an exception for submission of certifications before issuing approval. The ORRC Research Compliance Officer or the Director of ORRC may approve exceptions.

- The ORRC staff notifies the NCI CIRB administrative office, via email, that the IRB has accepted, rejected, or made minor modifications to the NCI CIRB review of the protocol.

- The NCI CIRB facilitated reviewer reviews modifications made by the PI.

- If approved, ORRC staff generates an approval letter and stamps the consent form. The ORRC staff assigns the approval period according to the approval period issued by the NCI CIRB.

- If the NCI CIRB protocol review is not acceptable to the HU IRB, the PI uses the HU ORRC application forms to complete the application process for HU IRB initial full review of the proposed protocol (See Initial Full Review SOPP).

- ORRC staff reports HU NCI CIRB activity to the IRB by placing it on the next available agenda.

16.4.4 Conflict of Interest

- Should the facilitated reviewer at HU have a conflict of interest, ORRC staff assigns an IRB Chair or a physician IRB member as an alternate to review the protocol and provide comments as outlined in the Submission section above.

16.4.5 Facilitated Review Outcome(s)

- The Facilitated Review IRB member reviews the NCI CIRB submission. There are three possible outcomes:
  - DEFERRED (NCI CIRB Protocol Review is Not Accepted): Local IRB oversight is required. The PI must prepare a protocol summary and submit HU IRB application materials to the HU IRB for full board review. The NCI CIRB is not involved in overseeing the protocol.
  - MINOR MODIFICATIONS REQUIRED: Specific stipulations must be addressed before the NCI CIRB is designated as the IRB of record.
  - APPROVED: The CIRB will be designated as the IRB of record. The PI receives a HU IRB approval certificate and the approved documents.

16.4.6 Post-Approval Responsibilities

Once the NCI CIRB is designated as the IRB of record, the PI interaction with the HU IRB is minimal but includes the following actions:

- Consent/Assent Form Revision: Informed consent forms must conform to the current HU IRB format including the standard statements to be added to the NCI CIRB informed consent template (See NCI CIRB Instructions). The PI must submit any revisions to the consent form initiated by the applicable cooperative group or mandated by the NCI CIRB to the HU IRB for approval whether it happens at NCI CIRB continuation review time or throughout the NCI CIRB approval period. Minor word substitutions or local context additions to the informed consent document by the local PI, to facilitate better comprehension by the local population, must be submitted to the HU IRB for review and approval.

- Amendments: The PI submits any locally initiated alterations/updates (e.g., advertisements, personnel or site changes) to the HU IRB for review and approval.

- Unanticipated Problems (UPs): The PI submits local UPs to the HU IRB (see HU Unanticipated/Anticipated Problem/Adverse Event Reporting SOPP).

- Protocol Violation: The PI submits local protocol violations to the HU IRB (see HU Protocol Violations SOPP).

- Continuation Review (CR): The PI does not submit CR materials to the HU IRB unless there are modifications that impact the HU IRB approved informed consent form such as new information impacting risk or local contact information.

- Noncompliance: The PI submits local noncompliance to the HU IRB (see HU Noncompliance SOPP).

- Study Closure: To close a NCI CIRB study at HU, the PI submits a memo to the HU IRB. No continuing review form is necessary.

- HIPAA: The PI submits HU Authorization or Waiver of Authorization forms to the HU IRB for review.

16.5 REFERENCES

21 CFR 50.25

21 CFR 56.111
45 CFR 46.108
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
45 CFR 46 Subparts C