SOP: 412
NATIONAL CANCER INSTITUTE
CENTRAL INSTITUTIONAL REVIEW BOARD

1. POLICY

The Central Institutional Review Board (CIRB) Initiative is sponsored by the National Cancer Institute (NCI) in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The University of Oklahoma Health Sciences Center (OUHSC) has joined the initiative for review of NCI-approved Children's Oncology Group (COG) Phase 2 and 3 protocols and Pilot protocols and Adult Phase 3 Cooperative Group protocols.

The NCI CIRB will conduct initial and continuing review of the above pediatric and adult research studies. The OUHSC IRB will conduct facilitated review through a subcommittee.

Specific Policies

1.1 Submission Requirements to the OUHSC IRB

Investigators applying for initial approval of a CIRB-approved protocol must submit the following to the OUHSC IRB:

- CIRB-approved protocol documents and the CIRB approval letter
- CIRB-approved informed consent document
- The submission requirements outlined in SOP 301, Research Submission Requirements.

1.2 Subcommittee Purpose and Composition

The OUHSC IRB subcommittee will conduct facilitated review of NCI CIRB-approved studies for consideration of local context issues and oversight of local performance for these studies. The subcommittee is comprised of the IRB Chair and two additional IRB members who will propose and approve additions to the research studies. This subcommittee will meet as needed but no more than twice per month. Quorum consists of two members of this subcommittee.

1.3 Subcommittee Review and Determinations

The IRB subcommittee reviews submissions to (1) determine on a case-by-case basis whether to accept the CIRB review as the review of record or to conduct its own review of the protocol and (2) determine whether there are local concerns that need to be addressed.

The IRB subcommittee shall make one of the following determinations as a result of its review of CIRB-approved protocols submitted for review:

- Accept the CIRB submission without changes.
- Accept the CIRB submission with de minimus modifications (see 7.2.3 below).
- Not accept the CIRB review and require that the investigator submit the protocol for review by the convened IRB.

1.4 Facilitated Review Acceptance

The OUHSC IRB notifies the CIRB Operations Office each time it accepts or rejects the CIRB review of a protocol by submitting a separate form to the CIRB for each protocol review that is completed. The CIRB becomes the IRB of Record for the protocol and is responsible for continuing review, subsequent amendments, and serious adverse events (SAE) as reported by

the cooperative group. The OUHSC IRB is responsible for review of local SAEs and oversight of local conduct of the study. See also Section 3.

1.5 HIPAA

Compliance with HIPAA regulations are considered local context issues and remain the purview of the OUHSC.

1.6 Special Populations

- Children. CIRB makes the determination whether assent of the child is required for studies involving children. The OUHSC IRB subcommittee makes the determination on whether and how to document assent.
- Incompetent Adults. CIRB makes the determination whether individuals with impaired decision-making capacity as a category are eligible for a study. The OUHSC IRB subcommittee will follow SOP 501, Special Populations and SOP 701, Consent Process and Documentation for studies including incompetent adults.
- Prisoners. CIRB is not constituted to review studies eligible for prisoner populations, per 45 CFR 46, Subpart C. If an investigator requests enrollment of prisoners on a particular study, the OUHSC IRB will review the study by the convened IRB.

2. SCOPE

These policies and procedures apply to investigators submitting CIRB-approved protocols for facilitated review, to IRB staff, and to IRB members of the subcommittee.

3. RESPONSIBILITY

The Responsibilities of the NCI CIRB are to:

1. Perform initial full board reviews of new research studies, discuss any issues with the Cooperative Group Study Chair, and make a final decision of approval or disapproval of the study;
2. Conducts Continuing Review and also reviews SAEs, study amendments, and all other documents submitted by the Study Chair;
3. Provide the CIRB application, primary reviewer reviews, outcome letters, minutes and other relevant documents to the OUHSC IRB;
4. Notify OUHSC IRB of any new materials that have been reviewed for an active study and any changes in the study approval status;
5. Maintain a board membership that satisfies the requirements of 45 CFR 46, 21 CRF 56, and provide special expertise as needed from board members or consultants to adequately assess all aspects of each study;
6. Make available to the OUHSC IRB the CIRB membership roster and the CIRB Standard Operating Procedures (SOP);
7. Provide CIRB members with proper initial and continuing education on topics relevant to protections of human participants;
8. Notify OUHSC IRB immediately if there is ever a suspension or restriction of the CIRB's authorization to review studies; and
9. Notify OUHSC IRB of any CIRB SOP decisions or regulatory matters that might affect OUHSC's reliance on CIRB reviews or performance of the research.

The Responsibilities of OUHSC are to:

1. Take actions to ensure the safe and appropriate performance of the research at OUHSC including, but not limited to, monitoring protocol compliance, managing major protocol violations, and any SAEs occurring at OUHSC. In addition, provide a mechanism by which complaints about the research can be made by local study participants or others;
2. Require that the investigators and other staff at OUHSC who are conducting the research are appropriately qualified and meet OUHSC's standards for eligibility to conduct research;
3. Provide to CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the OUHSC IRB, such as the OUHSC IRB administrator;
4. Establish a written procedure for facilitated review by which the OUHSC IRB will receive and review CIRB materials for studies to be performed at OUHSC. For each CIRB-reviewed study (approval or disapproval) that is submitted to the OUHSC IRB by an OUHSC investigator, the OUHSC IRB will:
    - Review the appropriate CIRB's materials (downloaded from www.ncicirb.org);
    - Determine if there are any local context issues that must be addressed by the OUHSC IRB;
    - Determine if the CIRB review is acceptable to the OUHSC IRB; and
    - Decide whether to accept the CIRB review or conduct a separate OUHSC full board IRB review.
5. Report to CIRB the decision about OUHSC acceptance/rejection of the CIRB review via the Facilitated Review Acceptance Form. Notify CIRB if there is ever a change in the acceptance/rejection of the CIRB review;
6. 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;
7. Maintain records for each CIRB-approved study opened at the OUHSC. Records include documentation of the decision and evidence that it has received and considered all CIRB material relevant to the study;
8. Maintain an OHRP-approved Assurance for the human subject research and an OHRP IRB registration number;
9. Maintain a human subject protection program compliant with 45 CFR 46 and 21 CRF 56;
10. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Guidance Document, IRB Knowledge of Local Research Context, 2000 Update

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations

SOP 501, Special Populations

SOP 701, Consent Process and Documentation

6 ATTACHMENTS

Facilitated Review Process Flowchart for CIRB

7. PROCESS OVERVIEW

7.1 OUHSC Procedures

7.1.1 Submission Procedures for Initial Review. An investigator who wishes to enroll participants in a CIRB-approved protocol downloads the IRB Facilitated Review Packet from the Participant side of the CIRB website and submits those documents to the OUHSC IRB, along with other appropriate submission documents (outlined in SOP 301, Research Submission Requirements). Only one original and three copies are required for this type of submission.

7.1.2. Subcommittee Determinations. The IRB subcommittee will take one of the following actions following its review of NCI CIRB-approved protocol submissions:

1. Accept the CIRB submission without changes.
2. Accept the CIRB submission with de minimus modifications.

   De Minimus Modifications: Local boilerplate additions to the informed consent dealing with state and local law, institutional requirements, or IRB policies may be added to the local consent form. No CIRB-approved information may be deleted from the informed consent document. The IRB subcommittee may also make minor word substitutions or additions in the informed consent document, particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB-approved contents. Additional risks may be added to the informed consent document. Revisions or changes to the local consent form other than those described above require review by the convened IRB and therefore facilitated review may not be used, and the CIRB cannot serve as the IRB of record for the protocol.
3. Reject the CIRB review and require that the investigator submit the protocol for review by the convened IRB.

7.1.3. The IRB Administrator notifies the CIRB Operations Office each time it accepts or rejects the CIRB review of a protocol by completing the Facilitated Review Acceptance form. The IRB Administrator notifies the investigator of the subcommittee's decision by email to accept or reject the CIRB's review.

7.1.4 Consent Form Stamping. CIRB provides the approval date and expiration date of the study. The IRB Administrator provides a copy of the stamped consent form using the dates provided by CIRB.

7.1.5 Continuing Review. The investigator downloads and prints all the documents from the Participants' Area of the CIRB website, including the consent form and re-approval letter, and submits these documents to the OUHSC IRB. One original and three copies are required for this type of review submission. The investigator is not required to submit the IRB Application for Continuing Review. The IRB Administrator provides a copy of the stamped consent form using the dates provided by the CIRB.

7.1.6 Protocol Amendments. Whenever the Cooperative Group makes protocol amendments, the investigator must use the CIRB-approved version. The investigator is not required to submit the IRB Protocol Modification Form to the OUHSC IRB.

7.1.7 Adverse Events. The investigator submits to the OUHSC IRB only local adverse events that are determined to be Unanticipated Problems as outlined in SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations. Only one original and three copies are required for this type of submission.

APPROVED BY: _____ **DATE: 01/15/2010**

NEXT ESTABLISHED REVIEW DATE: MAY 2012