

STANDARD OPERATING PROCEDURE FOR UTILIZING THE NCI CIRB

TITLE: Utilizing the NCI CIRB

1. **PURPOSE** - The purpose of this Standard Operating Procedure (SOP) is to outline the procedures for utilization of the National Cancer Institute's (NCI) Central Institutional Review Board (CIRB) using facilitated review. The NCI CIRB was designed to 1) improve access to NCI-sponsored Cooperative Group clinical trials for potential study participants and their physicians by enabling local IRBs to rapidly approve clinical trials through the use of a facilitated review process; 2) enhance the protection of study participants by providing consistent expert IRB review at the national level; and 3) reduce the administrative burden for local IRBs and research staff. Since this Institution has completed enrollment in the CIRB Initiative by submitting a completed CIRB Application, submitting two signed Authorization Agreements, and including the CIRB on the Institution's FWA, the local IRB and investigators may take advantage of the CIRB's reviews.

2. **POLICY** - It is the policy of the local IRB (Human Assurance Committee) to perform a facilitated review of all NCI-sponsored Cooperative Group studies approved through the NCI CIRB in which the Institution wishes to participate. The HAC decides on an individual study basis whether to accept the CIRB review or to perform full IRB review of the study.

3. **RESPONSIBILITY** – If the CIRB's review is accepted, the CIRB becomes the IRB of Record for the study and is responsible for reviews of amendments, continuing reviews, review of adverse events distributed by the Cooperative Group coordinating the study, and review of information distributed by the Cooperative Group coordinating the study intended for use by current or prospective study participants. The HAC and Institution are responsible for consideration of local context and oversight of local performance for these studies.

4. **REFERENCE DOCUMENTS**

Authorization Agreement Between the NCI Central IRB and Relying Institution
CIRB Quickguide to Facilitated Review
CIRB Division of Responsibilities Between the Central IRB and Enrolled Local Institutions

5. **PROCEDURE FOR INITIAL REVIEW**

When an investigator wishes to open a Cooperative Group clinical trial which has been approved by the NCI CIRB, the following steps must be followed to conduct a facilitated review:
 - A. The investigator/research staff will submit one copy of each of the following documents obtained from the CIRB Website (www.ncicirb.org)
 1. CIRB Application.
 2. Study protocol.

3. CIRB final approval letter.
4. CIRB approved informed consent document.
5. Informed consent document on Institutional letterhead
6. Correspondence
7. Any SAE reports
8. Amendments
9. Primary Review
10. Minutes of the meeting

CIRB study submissions are subject to the same agenda deadline as other IRB agenda submission items.

The investigator will include the OHRP Ancillary IRB Review form with the submission.

All facilitated review items will be emailed to HAC@mcg.edu using the email template provided during the initial training session.

- B. All new CIRB protocols listed for review will have a facilitated review performed by the HAC Vice-Chair. The Vice-Chair will consider local context issues when reviewing the study and informed consent document.
- C. Local context issues include, but are not limited to: local and state laws; institutional policies; local investigator credentials; and demographics/cultural issues of the local population. Minor word substitutions and/or additions to the informed consent document to aid in comprehension by the local population are permitted so long as the changes do not alter the meaning of the text. Deletions are not allowed. If the HAC requires text changes that alter the meaning of the text, the protocol will require full board review by the HAC, facilitated review may not be used, and the CIRB cannot serve as the IRB of record for the protocol at the local site.
- D. The HAC Vice-Chair shall determine whether to accept the CIRB review of the study or whether to require that the study be submitted for full review by the HAC. Review comments, if any, and the decision to either accept or not accept the CIRB review shall be sent to the IRB Coordinator via email within 2-3 business days of review.
- E. The local IRB Coordinator will notify the CIRB Administrative Office of facilitated review acceptance via the website within 24 hours of notification of Vice-Chair's decision.
- F. The IRB Coordinator will list the study on the upcoming IRB agenda in the "facilitated review" category. Studies designated for full HAC review will be listed on the following month's agenda for such review.
- G. The expiration date of CIRB studies will be the CIRB expiration date.
- H. For CIRB studies accepted by the HAC, the CIRB will become the IRB of record for the protocol, and the CIRB will be responsible for continuing review

as well as review of subsequent amendments and non-local, serious adverse events as notified by the cooperative group.

- I. Documentation of the facilitated review acceptance by the HAC Vice-Chair of a new CIRB study will be noted in the HAC minutes.
- J. A copy of the initial review documents will be maintained in the HAC study file.

6. PROCEDURE FOR CONTINUING REVIEW OF A CIRB-APPROVED STUDY

The CIRB conducts continuing review for all studies on its menu. The HAC does not have to conduct a continuing review for studies for which the CIRB is the IRB of record.

7. PROCEDURE FOR AMENDMENT REVIEW OF A CIRB-APPROVED STUDY

The CIRB reviews amendments for all studies on its menu. Amendments to a CIRB-approved study will not be reviewed by the HAC. When changes in an amendment include changes in the informed consent document, the investigator/research staff will submit one copy of the updated informed consent document to the HAC for date stamping.

8. PROCEDURE FOR SERIOUS ADVERSE EVENT REVIEW

Serious adverse events or unanticipated problems that do not involve study participants from this Institution should not be submitted to the HAC. Serious adverse events or unanticipated problems involving a study participant from this Institution should be submitted in the usual manner per HAC Standard Operating Procedures.

9. TRANSFER OF STUDIES CURRENTLY APPROVED BY LOCAL IRB TO CIRB

Cooperative Group studies currently approved by the HAC may be transferred to the CIRB. Each study should be submitted to the HAC as an Initial Review (see Section 5 for detailed process) and the facilitated review should be reported to the CIRB and included in the local IRB minutes as outlined in Section 5. For studies transferred to the CIRB, a note-to-regulatory file should state that the protocol was transferred to the CIRB with an effective date the same as the date the NCI CIRB Facilitated Review Acceptance Form was submitted to the CIRB. Enrolled study participants do not have to be re-consented as the Institution's informed consent document will continue to be used and the study remains under HAC oversight of performance.