National Cancer Institute

Central Institutional Review Board

Handbook for Local Sites
NCI CIRB Handbook for Local Sites

Additional copies are available from the CIRB Website (http://www.ncicirb.org) or by mail from:

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401 N. Washington St., Suite 700  
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A Word from the NCI...

Welcome to the NCI Central Institutional Review Board (CIRB) Initiative.

Comprised of multidisciplinary experts and patient advocates dedicated to the field of oncology, the CIRB offers high quality IRB reviews for use by local IRBs in place of local IRB review. When the CIRB is used as instructed in this Handbook, IRB and research staff will benefit from the decrease in time and effort required for approval of the Cooperative Group studies on the CIRB menu.

Thank you for your joining with us in this partnership. If you have any questions, contact the NCI CIRB Helpdesk at 1-888-657-3711, or via email at ncicirbcontact@emmes.com.

Sincerely,

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Head, CIRB Initiative

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Mission of the NCI CIRB Initiative

The mission of the National Cancer Institute’s Central Institutional Review Board (CIRB) Initiative is to reduce the administrative burden on local IRBs and investigators by partnering with local IRBs to provide a high level of protection for study participants in NCI’s Cooperative Group clinical trials.
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1.0 Introduction

This handbook is intended to assist institutions, local Institutional Review Boards (IRBs), investigators, and research staff to understand the purpose of the Central Institutional Review Board (CIRB) Initiative and the intended design of this innovative IRB review model. Information outlining the responsibilities of the CIRB and local institutions and their IRBs is provided in this handbook as well as suggestions to consider when incorporating the CIRB into local IRB processes. The CIRB Operations Office welcomes feedback to continually improve the content of this handbook.

The CIRB follows 45 CFR 46 and 21 CFR 50 and 56. The Adult CIRB reviews all Phase 3 treatment trials coordinated by the NCI Clinical Trials Cooperative Groups (ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG, and SWOG). The Pediatric CIRB reviews COG Pilot, Phase 2, and Phase 3 treatment trials. The term ‘CIRB’ refers to both Adult and Pediatric CIRBs unless otherwise stated.

2.0 Background of CIRB Initiative

2.1 The Armitage Report Recommendation

In 1996, the National Cancer Institute (NCI) Clinical Trials Program Review Group was tasked with addressing the challenge of responding to expanding opportunities of new therapeutics and technology while reducing costs of research through efficiencies. The Review Group met six times over an 11-month period and its recommendations, known as “The Armitage Report,” included establishing a “streamlined IRB process” for multi-center trials such as those coordinated by the NCI’s Clinical Trials Cooperative Group Program. The Armitage Report is located at the following URL:

http://deainfo.nci.nih.gov/advisory/bsa/bsa_program/bsactprgmin.pdf

Due to the importance of investigators from multiple sites using a single version of a protocol, local IRBs reviewing Cooperative Group trials could not make any changes in the protocol and were restricted to approving the protocol supplied by the Cooperative Group or not approving the study for participation at their institution. This situation resulted in redundant reviews across the nation as local IRBs reviewed the same protocol without the ability to effect changes that could potentially improve study participant protections.

In response to the Armitage Report’s recommendation to streamline the IRB process, the NCI worked in conjunction with the Office for Protection from Research Risks (OPRR), now known as the Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA) to create the Central Institutional Review Board (CIRB) Initiative. The CIRB Initiative would create a more effective and efficient clinical research effort by conducting full board review centrally which could then be used by local IRBs, thus eliminating redundant processes.
2.2 Support for Central Review

The two primary regulatory bodies overseeing human subject protections, OHRP and FDA, have publicly supported central review. Quoting from a recent OHRP Request for Information, “If institutions become more willing to rely on cooperative review arrangements and on review of IRBs operated by other institutions or organizations, OHRP believes that this will reduce administrative burdens associated with implementing 45 CFR part 46 without diminishing human subject protections.” Additionally, SACHRP, the Secretary’s Advisory Committee on Human Research Protections has endorsed central review in a letter to the Secretary of Health and Human Services located at the following URL:
http://www.hhs.gov/ohrp/sachrp/sachrpletter091808.html

The FDA supports central review by regulation in 21 CFR 56.114, “...institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.”

The FDA has also issued guidance in support of centralized review titled “Guidance for Industry: Using a Centralized IRB Review Process in Multicenter Clinical Trials” located at the following URL:

2.3 Choosing a Model

OHRP has issued a guidance titled “IRB Knowledge of Local Research Context” which describes the standards applicable when an institution with a Federalwide Assurance (FWA) wishes to rely on another IRB. The document is located at the following URL: http://www.hhs.gov/ohrp/policy/local.html.

Included in the OHRP’s guidance, in Sections B.2.i and B.2.ii, are two design models that may be used for systems providing central IRB reviews. For ease of reference, the CIRB refers to the model in Section B.2.i as Model A with Model B referring to the model described in Section B.2.ii.

- Model A is traditionally used by commercial IRBs and is characterized by the central IRB providing review of study-specific documents as well as having responsibility to identify and address local context issues. Model A may be used for institutions without IRBs or in lieu of an institution’s IRB.

- Model B may be used for institutions that have a local IRB and is designed to partner the central and local IRB’s efforts to provide human subject’s protections. The central IRB is tasked with providing reviews which may be used by participating local IRBs with the local IRBs addressing local context issues.

The NCI CIRB chose to design the CIRB Initiative after Model B for several reasons: local IRBs provide key value as they are best positioned to understand and
address local context issues; local IRBs retain oversight of the conduct of the
research; local IRBs retain decision-making regarding using the CIRB; and
maximizing the value of the expertise of local IRBs to address local context issues
promotes efficiency.

3.0 Facilitated Review

3.1 Definition of Facilitated Review

‘Facilitated Review’ is defined as the review process used by local IRBs as they
make the determination whether or not to accept the CIRB’s review of a
Cooperative Group study. The CIRB has the responsibility of conducting a full
board initial review. The CIRB has the ability to request changes in the protocol
and Cooperative Group’s model informed consent document in an effort to improve
human subject’s protection. The CIRB also has responsibility for review of the
following: amendments, both those requiring full board review or expedited
review; continuing reviews; recruitment or educational materials intended for use
by current or potential study participants; and review of adverse events distributed
by the Cooperative Group to investigators.

Once the CIRB has approved a study, IRBs from institutions enrolled in the CIRB
Initiative are able to perform a facilitated review and open the study in a much
shorter time than required by the traditional local full board IRB review process.

Once a local IRB has performed a facilitated review and reported it to the CIRB via
the CIRB Website, the CIRB becomes the IRB responsible for review for that
specific study. Facilitated review is a one-time review for the life of the study.
Because the CIRB is responsible for all subsequent reviews, the local IRB is no
longer required to conduct reviews of amendments, both those requiring full board
review or expedited review; continuing reviews; reviews of recruitment or
educational materials prepared by the Cooperative Group and intended for use by
current or potential study participants; and review of adverse events distributed
by the Cooperative Group to investigators.

3.2 How to Conduct a Facilitated Review

As always, the institution or investigator makes the decision whether or not a study
may be opened at their institution. Once the decision to open the study has been
made, local IRBs enrolled in the CIRB Initiative have the prerogative to use the
CIRB’s review or conduct their own local full board review on a study-by-study
basis.

The CIRB performs full board review required by 45 CFR 46.111 for adult Phase 3
and pediatric Pilot, Phase 2, and Phase 3 Cooperative Group studies. Upon CIRB
approval, the CIRB posts the CIRB review documents on the CIRB Website in the
Participant’s Area. The Participant’s Area of the website may be reached by
clicking on the banner link found on the CIRB’s homepage at www.ncicirb.org.
Detailed instructions on downloading review documents from the CIRB Website
are located in Section 8 “Navigating the Participant’s Area of the CIRB Website”. 
Local IRB or research staff downloads the documents from the website and submits them to the local IRB Chair for review.

**Note:** If the local IRB Chair prefers, a subcommittee may be designated to perform the facilitated review, however, local IRBs are encouraged to limit the size of the subcommittee to a few reviewers in an effort to maximize the time and effort saved by using the CIRB’s review.

The Chair or subcommittee reviews the downloaded documents to identify any local context considerations that would preclude using the CIRB review. For example, the Chair or subcommittee should consider the following topics that impact the conduct of research at your institution:

- Local population,
- Local institution credentials,
- Institution policies,
- State and local laws, and
- Local and Professional Community Standards.

If there are no concerns related to local context, the Chair or subcommittee can decide to accept the CIRB’s review in lieu of their own local full board review. The Chair or subcommittee retain the option to not accept CIRB review and can choose to conduct their own local full board review for a particular study. The informed consent document may be revised per the Cooperative Group’s guidelines to comply with state and local laws; professional and community standards; institutional policies, such as applying the institution’s letterhead and adding local contact information; and the needs of differing populations. However, no text should be deleted, nor should additions or modifications change the meaning of any sections. If revisions/changes to the informed consent document other than those described above are deemed necessary, a full Board review at the local level is required and facilitated review may not be used.

To complete the facilitated review process, it is necessary for the local IRB to inform the CIRB of their acceptance of the CIRB’s review for the specific study. The local IRB staff member, as designated in Section B on the NCI CIRB Institution Enrollment Worksheet submits the Facilitated Review Acceptance Form via the study-specific webpage on the CIRB Website. Completion and submission of the Facilitated Review Acceptance Form is discussed in more detail in Section 8.5 of this Handbook titled “Reporting the Facilitated Review Acceptance”. When the CIRB receives the Facilitated Review Acceptance Form, an emailed response acknowledging that the CIRB is the IRB responsible for review for the specific study open at the institution is sent to the person submitting the Facilitated Review Acceptance Form. Once the Facilitated Review Acceptance Form has been submitted and the acknowledgment email received, the documentation is complete. The CIRB is the IRB responsible for the review for the particular study and
performs all future continuing reviews and amendment reviews as well as reviews of recruitment/educational materials and Adverse Events (AEs) distributed by the Cooperative Group for the life of the study. The local IRB no longer has the responsibility for these reviews; however, the local IRB maintains responsibility for ensuring that the informed consent document addresses local context considerations.

For your convenience, the CIRB Operations Office has compiled a Facilitated Review Packet. The Facilitated Review Packet consists of the protocol, the CIRB’s version of the Group’s model informed consent document, the CIRB Application, the scientific and lay primary reviewers’ comments, the minutes from meeting(s) where the study was reviewed, correspondence between the CIRB and the Study Chair/Cooperative Group leading the study, and any other documents used in initial review. The Facilitated Review Packet may be submitted to the local IRB Chair/subcommittee for facilitated review. The packet is located on the Participant’s Area of the CIRB Website (http://www.ncicirb.org/CIRB_Login.asp) on the study-specific webpage.

Use of a Facilitated Review Packet is optional. Each IRB may supplement or replace contents of the Facilitated Review Packet by downloading individual documents from the website, as desired.

3.3 When to Conduct Facilitated Review

For pediatric trials, the CIRB has approved the study prior to distribution of the study by COG so local IRBs and research staff may access the documents and conduct facilitated review any time after the study has been distributed by COG.

For adult trials, a process change occurred in May 2009 affecting the timing of the CIRB’s review. The sequence of review has been redesigned such that when the NCI’s Cancer Therapy Evaluation Program provides approval of the trial, it is forwarded simultaneously to the CIRB and Cooperative Group. The CIRB will conduct its review of the trial at the same time that the Cooperative Group completes its final preparations to distribute the study to investigators.

It is anticipated that by allowing the Cooperative Group to make its final preparation for study distribution while the CIRB conducts its review, the total time to distribution of Adult Phase 3 Cooperative Group trials may be shortened.

If the Cooperative Group completes final preparation and is ready to distribute the trial prior to CIRB approval, it may proceed with distribution of the trial. In this case, notification will be posted to the CIRB Website indicating the CIRB meeting date when the trial will be reviewed as well as an estimated CIRB approval date.

In summary, at time of study distribution by the Cooperative Group, one of two scenarios will occur for local IRBs and research staff:

- If the CIRB has completed its review of the trial prior to Cooperative Group distribution, the trial will be CIRB-approved at time of distribution and the
CIRB’s review may be immediately used. The Facilitated Review Packet will be in place and all review documents will be posted on the study-specific webpage of the CIRB Website. It is the goal of the CIRB Operations Office to have the study approved and documents available to local IRBs and research staff at the time the trial is distributed by the Cooperative Group.

- In the event that the Cooperative Group distributes the trial prior to completion of CIRB review, local IRBs who wish to use the CIRB’s review must wait until they are notified by the CIRB of study approval. This will be done via a study-specific approval notification email which will be sent to all IRB and research staff for which an email address is contained in the CIRB database. While the study is in CIRB review, information will be posted on the study-specific CIRB webpage indicating the CIRB meeting date when the trial will be reviewed as well as an estimated CIRB approval date. When the study has been CIRB approved, the approval notification email will be distributed and the review documents, including the Facilitated Review Packet, will be posted on the CIRB Website, per the usual process.

If the protocol was changed during CIRB review, the Cooperative Group will distribute an amendment encompassing all of the modifications that occurred during CIRB review. Sites with local IRB approval of the study (i.e. sites that did not wait for CIRB approval or are not enrolled in the CIRB) must submit this amendment to their local IRB for review.

Sites enrolled in the CIRB Initiative are encouraged to wait for CIRB approval and conduct facilitated review.

3.4 Transferring an Institution’s Menu of Cooperative Group Trials to the CIRB

A local IRB may wish to transfer to the CIRB some or all Cooperative Group trials already open at the institution. This type of transfer is permitted provided the study is on the CIRB menu. A facilitated review must be performed and reported via the CIRB’s Website for each study individually. There is no limit on how many studies for which an institution may conduct facilitated review and rely on the CIRB’s reviews.

3.5 Transferring Review Responsibilities for a Study Back to the Local IRB

Local IRBs sometimes request to transfer review responsibilities for a study back to the local IRB. The CIRB utilizes an electronic process for local IRB staff to transfer review responsibilities for a study from the CIRB back to the local IRB. Once a local IRB has regained review responsibilities from the CIRB, the local IRB follows its own procedures for all subsequent reviews of that study. Only local IRB staff members with permission to submit the Facilitated Review Acceptance Form are able to transfer review responsibilities for a study back to the local IRB. Review responsibility transfers are study-specific just as facilitated reviews are study-specific.
If a local IRB wishes to transfer review responsibilities for a study and study participants are enrolled at the institution, the study must first be opened via full board local IRB review and approval. This is necessary to ensure there are no gaps in IRB coverage for the study participants during the transfer of review responsibility. A copy of the study-specific local IRB full board review approval letter is required as a part of the transfer process.

Note: For studies that have previously been opened at the institution and transferred to the CIRB that the local IRB now wishes to regain review responsibility, another local IRB full board review, dated after the facilitated review date, must be done if there are study participants enrolled. The original full board review conducted by the local IRB, predating the use of the CIRB, is no longer in effect.

See Section 8.7 “Closing or Transferring Review Responsibility for a Study Back to the Local IRB” for detailed instructions for completing the Study Closure or Review Responsibility Transfer Form (SCRRTF). Once the SCRRRTF has been submitted and the acknowledgment email received, the process is complete. The local IRB is now responsible for the review of the study transferred and performs all subsequent reviews of that study in accordance with its own procedures.

3.6 Closing a Study

Local IRBs sometimes request to close a study for reasons including no accrual of patients. The CIRB utilizes an electronic process for local IRB staff to close a study.

See Section 8.7 “Closing or Transferring Review Responsibility for a Study Back to the Local IRB” for detailed instructions for completing the Study Closure or Review Responsibility Transfer Form (SCRRTF). Once the SCRRRTF has been submitted and the acknowledgment email received, the process is complete. The study is now closed with the CIRB.

3.7 Requirement for Number of Facilitated Reviews Conducted

There is no minimum or maximum requirement for the number of facilitated reviews a local IRB enrolled in the CIRB Initiative conducts. Local IRBs are the decision-makers and choose to use the CIRB on a study-by-study basis.

3.8 Participation Fee

The NCI does not charge a fee for participation in the CIRB Initiative.

4.0 CIRB’s Own Version of the Informed Consent Document (ICD)

For pediatric trials, the version of the ICD that is reviewed by the Pediatric CIRB is COG’s model ICD. Since the Pediatric CIRB reviews and approves COG’s model ICD, there is no other version
of the ICD. Local IRBs and research staff should use COG’s model ICD when considering local context.

For adult trials, beginning in May 2009, the Adult CIRB has its own version of the ICD. The CIRB’s version of the ICD is based on the Group’s model ICD and reflects any changes made by the CIRB to increase study participant’s protections or understanding of the study. All changes appearing in the CIRB’s own version of the ICD have been approved by the Study Chair/Cooperative Group. It is important for local IRBs conducting a facilitated review of an adult study to download and use the CIRB’s version of the ICD from the CIRB Website. Revising the CIRB’s version of the ICD to accommodate local context considerations is permitted and the revisions should comply with the lead Cooperative Group’s guidelines pertaining to revising the ICD.

5.0 Responsibilities of the Enrolled Local Institution/IRB

The following responsibilities are described in the “Division of Responsibilities between the Central IRB and Enrolled Local Institutions” located at the following URL: http://www.ncicirb.org/Division%20of%20Responsibility.pdf. This document accompanies the Authorization Agreement.

5.1 Research Performance

Ensure the safe and appropriate performance of the research at its institution. This includes, but is not limited to, monitoring protocol compliance, managing any major protocol violations, managing any serious adverse events occurring at the institution, ensuring qualifications of research staff and providing a mechanism by which complaints about the research can be made by local study participants or others.

5.2 Providing Contact Information

Provide the names and addresses to the CIRB Operations Office of local contact persons who have authority to accept a facilitated review and/or correspond on behalf of the local IRB (e.g. the local IRB Director).

5.3 SOP for Facilitated Review

Establish a written procedure for performing facilitated review.

5.4 Regulatory File

Maintain records for each CIRB approved study opened at your institution as per your local institution policy.

5.5 FWA and IRB Registration Number

Maintain an OHRP-approved Assurance for human subject’s research and an OHRP IRB registration number.
5.6 Human Subjects Protection Program

Maintain a human subject’s protection program compliant with 45 CFR 46 and 21 CFR 56.

5.7 Compliance with Regulations/Requirements

Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.

Also included in the “Division of Responsibilities between the Central IRB and Enrolled Local Institutions” document is this additional information delineated by topic:

5.8 Assent (for pediatric trials)

The CIRB makes the determination whether assent of the child is required. Whether and how to document assent is the purview of the local institution per 45 CFR 46.408(e).

5.9 HIPAA

Compliance with HIPAA regulations is considered a local context consideration and remains the purview of the local institution and local IRB.

5.10 Incompetent Adults

The CIRB determines whether ‘individuals with impaired decision making capacity’ as a category are eligible for a study. The local institution must follow state law and institutional policy regarding the authority of legal guardians to consent to research, as well as documentation of proxy consent.

5.11 Informed Consent Document

As part of facilitated review, the local IRB Chair/subcommittee may;

- Apply local boilerplate requirements to the informed consent document to comply with state or local laws, institutional requirements, or IRB policies.

- Make minor word substitutions or additions in the informed consent document to facilitate better comprehension by the local population as long as the proposed changes do not alter the meaning of the CIRB-approved contents and the changes comply with the Cooperative Group guidelines regarding informed consent document changes. The informed consent text may not be otherwise deleted or contradicted.

Revisions/changes to the informed consent document other than those described above require full Board review at the local level, and facilitated review may not be used.
The translation of the informed consent document is the responsibility of the local institution.

5.12 Prisoners

The CIRB is not constituted to review studies for participation by prisoners, per 45 CFR 46 Subpart C, so cannot be the IRB responsible for review if the local investigator wants to enroll a prisoner. If the local investigator wants to enroll prisoners on a particular study, the local IRB must conduct a full board review of the study as per Federal regulations.

5.13 Serious Adverse Events (SAEs)

Serious adverse events that occur at the local institution must be reported to the local IRB as per local institutional policy and should not be reported to the CIRB. The investigator should report SAEs to the Cooperative Group per the study protocol.

5.14 Reporting Unanticipated Problems

5.14.1 Local unanticipated problems occur at and are limited to a specific institution. The local institution is responsible for managing these according to its FWA and local institutional procedures. If the local IRB determines that an unexpected incident, event or outcome meets the regulatory definition of unanticipated problem, it is the local institution’s responsibility to report it to OHRP/FDA.

5.14.2 Unanticipated problems within the purview of the CIRB are those unexpected incidents, events or outcomes which the sponsor identifies and which impact the trial nationally. These are reviewed by the CIRB and the CIRB accepts the responsibility to ensure reporting to the appropriate agency, i.e. OHRP and/or FDA.

6.0 Responsibilities of the CIRB

The following responsibilities are excerpted from the “Division of Responsibilities between the Central IRB and Enrolled Local Institutions” located at the following URL: http://www.ncicirb.org/Division%20of%20Responsibility.pdf. This document accompanies the Authorization Agreement.

6.1 Initial Review

Perform initial full Board reviews of new studies, discuss any issues with the Cooperative Group Study Chair, require modifications to be made by the Study Chair, and make a final decision of approval or disapproval of the study.

6.2 Other Reviews

6.2.1 Continuing Review
Perform Board review of all continuing reviews, discuss any issues with the Cooperative Group Study Chair, require modifications to be made by the Study Chair, and make a final decision of approval or disapproval of the continuing review.

6.2.2 Study Amendments

Perform Board reviews of all study amendments, discuss any issues with the Cooperative Group Study Chair, require modifications to be made by the Study Chair, and make a final decision of approval or disapproval of the study amendment.

6.2.3 Individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or other monitoring body.

Individual Adverse Event Reports distributed by the Cooperative Groups for studies which have a DSMB or other monitoring body do not receive CIRB review. The CIRB reviews the DSMB report and the study report at the time of continuing review as recommended in the following Guidance’s:


6.2.4 Conduct review of all other documents submitted by the Study Chair.

6.3 Documentation

Provide the CIRB Application, primary reviewer reviews, outcome letters, minutes and other relevant documents to the designated IRB at the local institution.

6.4 Notification of New Materials

Notify each local institution of new materials that have been reviewed for an active study and any changes in the study approval status.
6.5 Board Membership

Maintain a 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.

6.6 Membership Rosters and SOPs

Make available to the local institution the roster of CIRB membership and the CIRB Standard Operating Procedures. The roster of CIRB membership is located at the following URL: http://www.ncicirb.org/cirb_roster_brief.asp. The CIRB Standard Operating Procedures is located at the following URL: http://www.ncicirb.org/CIRB_SOPs.pdf.

6.7 Member Education

Ensure that CIRB members receive orientation and continuing education on topics relevant to human subject’s protection.

6.8 Notification of Suspension of Authorization

Notify the local institution immediately if there is ever a suspension or restriction of the CIRB’s authorization to review a study.

6.9 Notification of SOP Changes

Notify the local institution of any changes in CIRB SOPs that might affect the institution’s reliance on CIRB reviews or performance of the research at the local institution.

7.0 How to Enroll in the CIRB Initiative

7.1 Enrollment Support

The CIRB Operations Office has a staff person dedicated to assisting local IRBs with enrolling in the CIRB Initiative. To place a request for this type of assistance, contact the CIRB Helpdesk by phone (1-888-657-3711) during the hours of 8:00 AM and 4:00 PM ET or via email at ncicirbcontact@emmes.com.

7.2 Temporary Website Access for Interested Institutions

Institutions interested in the CIRB may receive usernames and passwords which grant 30-day access to the restricted side of the CIRB Website, known as the Participant’s Area. This temporary access to the CIRB’s review documents is intended to assist the local IRB’s decision regarding enrolling in the CIRB Initiative. If persistent questions remain, a conference call with local IRB or institutional staff may be arranged, if requested, to discuss the CIRB Initiative and facilitated review in more detail.
7.3 Eligibility Requirements

Institutions with IRBs reviewing Cooperative Group clinical trials are encouraged to enroll in the CIRB Initiative. Once enrolled in the CIRB Initiative, local IRB and research staff will be given access to the CIRB review documents. The institutional eligibility requirements for enrollment in the CIRB Initiative are as follows:

- The institution must have their own IRB.
- The institution’s IRB must currently be reviewing Cooperative Group adult Phase 3 clinical trials and/or pediatric Pilot, Phase 2 or Phase 3 clinical trials.

Institutions meeting the above eligibility requirements are welcome to enroll in the CIRB Initiative. Some institution’s IRBs depend on other IRB’s reviews of Cooperative Group trials rather than conducting their own full board review. In the CIRB Initiative, IRBs who depend on other IRBs for reviews are referred to as ‘dependent’ IRBs.

Please note: Dependent IRBs should not enroll in the CIRB Initiative. Only institutions with the IRB responsible for IRB review should enroll in the CIRB Initiative.

7.4 Steps of Enrollment

To enroll in the Initiative, institutions must do the following:

- Complete the NCI CIRB Institution Enrollment Worksheet
- Complete and submit two original Authorization Agreements

Instructions for completing the required forms are included in sections 7.4.1 and 7.4.2.

All required forms are posted at the URL: [http://www.ncicirb.org/CIRB_Join.asp](http://www.ncicirb.org/CIRB_Join.asp). Locate the box labeled ‘Related Links’ and click on ‘Enrollment Packet’. An Enrollment Packet webpage will open which contains links to the required forms as well as other helpful documents. The direct link to the Enrollment Packet is located at the following URL: [http://www.ncicirb.org/CIRB_Enrollment_Packet.asp](http://www.ncicirb.org/CIRB_Enrollment_Packet.asp).

7.4.1 Guidelines for Completing the NCI CIRB Institution Enrollment Worksheet

The direct link to the NCI CIRB Institution Enrollment Worksheet is located at the following URL: [http://www.ncicirb.org/NCI_CIRB_Enrollment_Worksheet.doc](http://www.ncicirb.org/NCI_CIRB_Enrollment_Worksheet.doc).
• Section A: Information About the Enrolling Institution

• Section B: Information About IRBs At Affiliate Institutions Who Rely on your IRB(s) at Your Institution

• Section C: Information About Affiliate Institutions Without IRBs Who Rely on your IRB(s) at Your Institution

Within the NCI CIRB Institution Enrollment Worksheet, there are specific instructions for completing each section. Each section also provides multiple tables to accommodate those institutions with a large amount of information to report. Although the number of tables may be more than enough for most institutions, if your institution requires more space to report information, please contact the NCI CIRB Helpdesk at ncicirbcontact@emmes.com.

Upon completion, the NCI CIRB Institution Enrollment Worksheet should be saved using Microsoft Word and returned via email to the NCI CIRB Helpdesk at ncicirbcontact@emmes.com.

7.4.2 Instructions for Completing the Authorization Agreement


It is necessary to complete, sign, and submit two original CIRB Authorization Agreements. Both original CIRB Authorization Agreements will be executed by the NCI. One will be returned to the enrolling institution for their records with the other retained by the CIRB Operations Office. It is the Institutional Official for the enrolling institution who should sign the CIRB Authorization Agreement.

Note: OHRP does not require dependent IRBs, which are those using the reviews of the local IRB at the enrolling institution, to sign a CIRB Authorization Agreement with the CIRB.

• The first two lines have been prefilled with the Organization Name (National Cancer Institute), Organization Number (IORG0000460), and IRB Registration Numbers for both the Adult CIRB (IRB00000781) and Pediatric CIRB (IRB00004296).

• Where requested, provide your institution’s name, FWA Number, and IRB Registration Number.

• In the next section, supply the same information for other institutions whose IRBs rely on your institution’s IRB. If no IRBs
rely on your institution’s IRB, state ‘None’ in this section. This information should match Sections B and C on the NCI CIRB Institution Enrollment Worksheet.

- Insert your institution name in the first sentence of the next paragraph where indicated by bolded font.

- In the next paragraph, check the appropriate box for which CIRB your IRB wishes to use: Adult CIRB, Pediatric CIRB, or you may check both boxes, if applicable. Again, insert your institution name in this sentence where indicated by bolded font.

- Print the name and title of the Signatory Official for your institution on the line where requested.

- The Signatory Official should sign and date the signature on the line below the printed name.

- Two original hard copies of the CIRB Authorization Agreement should be submitted to the CIRB Operations Office where they will be forwarded to the NCI for signature.

- One fully executed CIRB Authorization Agreement will be returned to you with the second being retained in the files of the CIRB Operations Office.

7.5 Confirmation of Completion of Enrollment

The CIRB Operations Office will verify that all enrollment steps have been completed and will return one executed Authorization Agreement to the enrolling institution. At this point, the CIRB Operations Office will issue usernames and passwords to all IRB and research staff listed on the NCI CIRB Institution Enrollment Worksheet. Usernames and passwords are used to access the Participant’s Area of the CIRB Website where all study-specific documentation is available. The IRB person(s) indicated in Section B on the NCI CIRB Institution Enrollment Worksheet as the individual(s) with the responsibility to report use of a facilitated review has a unique level of access to the CIRB Website. No other users have the ability to submit the Facilitated Review Acceptance Form.

It is very important to report to the CIRB Operations Office any changes in IRB staff that have password access to submit the Facilitated Review Acceptance Form (FRAF). Maintaining accurate identification of the person permitted to submit the FRAF will ensure email acknowledgements of FRAF submission will be sent to the appropriate email address. Failure to report this type of staffing change to the CIRB Operations Office may result in the inability of the local IRB to report the facilitated review. Without submission of the Facilitated Review Acceptance Form, the CIRB will not be assigned as the IRB responsible for review for the study.
Once usernames and passwords have been issued by the CIRB Operations Office, the local institution may begin to access the CIRB Website and conduct facilitated reviews.

7.6 Additional Enrollment Assistance

- The “Checklist for Incorporating the CIRB into Your Institution” may be found in the Enrollment Packet on the CIRB Website at the following URL: http://www.ncicirb.org/CIRB%20Checklist_1.13.09.doc  This Checklist will walk the user through the steps required to complete the enrollment process.

- A “Sample Standard Operating Procedure for Utilizing the NCI CIRB” has been drafted and is located at the following URL: http://www.ncicirb.org/Sample%20SOP%20for%20Utilizing%20the%20NCI%20CIRB%20-%2020090225.doc.  This sample SOP is an amalgamation of SOPs from various institutions who have successfully incorporated the CIRB into their review processes. The SOP may be used verbatim or piecemeal, whichever is more helpful to your institution, without crediting the CIRB.

8.0 Navigating the Participant’s Area of the CIRB Website

8.1 Accessing the Participant’s Area of the CIRB Website

The public CIRB homepage, as illustrated in Figure 1, can be located at the following URL: http://www.ncicirb.org.

Figure 1 – The public CIRB homepage
The Participant’s Area of the CIRB Website can be accessed by clicking on the link on the banner of the homepage titled “Participant’s Area”. This link takes the user to the CIRB Participant’s Login Screen (URL http://www.ncicirb.org/CIRB_Login.asp) as illustrated in Figure 2.

8.2 Entering Username and Password

The CIRB Operations Office issues usernames and passwords when an Institution’s enrollment requirements have been completed. The usernames and passwords are issued to everyone designated by the local IRB on the NCI CIRB Institution Enrollment Worksheet as requiring access to the Participant’s Area.

Users should enter their username and password in the appropriate box, as illustrated in Figure 2, and then click on ‘Go’ or press the ‘Enter’ button on your computer.

Users without usernames and passwords should inquire with your local IRB to ensure they have been included as requiring access. Names of additional users may be submitted to the CIRB Operations Office by the local IRB at any time. Usernames and passwords are usually issued within one week of the request.

8.3 Finding a Specific Study

Once the username and password are entered and accepted, a user is taken to the screen titled “CIRB Studies List” as illustrated in Figure 3. ‘Search’ criteria are located in the top box, and as few or as many criteria may be selected as the user wishes. Many users choose to search by Cooperative Group by completing the following steps:
1. Select a Cooperative Group from the “Choose a Group” category.
2. Press ‘Enter’ on your computer or click on the ‘Search’ button. This choice yields a scrollable list of all studies for that Cooperative Group on the CIRB menu.
3. Users also have the option of quickly viewing a specific Cooperative Group’s studies by clicking on the appropriate Group acronym in the “Quick Group List” located on the bottom of the screen as seen in Figure 3.

The second box on the “CIRB Studies List” screen, titled “Display Criteria for Study List”, permits the user to choose how the study list is presented. If no choice is selected, the studies are listed alphabetically by Group, if no Group was specified in the search criteria, and then numerically by Study Number.

![Figure 3 – CIRB Studies List](image)

8.4 Downloading the Facilitated Review Packet

The Facilitated Review Packet is located on the study-specific webpage. To download the documents, click on the “Facilitated Review Packet” hyperlink located in the middle of the screen, as shown in Figure 4. Alternatively, specific documents requested by the IRB may be downloaded individually and saved or printed for submission to the local IRB.
8.5 Reporting the Facilitated Review Acceptance

Once the local IRB has conducted facilitated review, the local IRB Administrator/Coordinator must complete and submit the Facilitated Review Acceptance Form via study-specific page on the CIRB Website.

**Note:** Only local IRB staff designated to accept facilitated review are able to view the Facilitated Review Acceptance Form link.

To complete the Facilitated Review Acceptance Form, follow these instructions:

1. Access the form by clicking on the hyperlink for the Facilitated Review Acceptance Form located in the red font text above the tab titles (Figure 4). Clicking this hyperlink will take you to the Facilitated Review Acceptance Form as seen in Figure 5.
2. Review the prefilled information on the Facilitated Review Acceptance Form. If you have any questions about the prefilled information, contact the CIRB Helpdesk for assistance.
3. Once the Facilitated Review Acceptance Form has been completed, click on the ‘Submit’ button at the bottom of the page.
4. A confirmation email will be sent to the IRB Contact submitting the form and anyone else included in the ‘Additional recipients’ box. This confirmation email acknowledges that your IRB has accepted the CIRB’s review and that the CIRB is now the IRB responsible for review for this study for your institution.
5. Upon receipt of the confirmation email, document the facilitated review for this study in your regulatory files per your local procedures.
Figure 5 – Facilitated Review Acceptance Form (FRAF)
8.6 Finding Out What Facilitated Reviews Have Been Reported for Your Institution

Once a username and password have been accepted, the user will land on the CIRB Studies List webpage, as indicated by the arrow in Figure 6. Above the list and below the banner, is a statement “Click here for Facilitated Reviews previously accepted at your institution.” This statement is a hyperlink to the list of FRs that has been reported for your institution. If any questions arise regarding the content of the list, please contact the CIRB Helpdesk immediately at 1-888-657-3711.

8.7 Closing or Transferring Review Responsibility for a Study Back to the Local IRB

To close or transfer review responsibility for a study back to the local IRB, a “Study Closure or Review Responsibility Transfer Form” (SCRRTF) must be completed and submitted as described below.

1. Access the list of Facilitated Reviews previously accepted at your institution as described in Section 8.6.
2. Click on the hyperlink, “If your IRB wants to close or transfer the review responsibilities to your IRB for any of these studies, click here” located at the bottom of the page, as indicated by the arrow in Figure 7.

Note: Only Local IRB staff designated to submit the Facilitated Review Acceptance Form are able to view the link to transfer a study.
Figure 7 – Facilitated Review (FR) Submission Report

To complete the SCRRTF (See Figure 8, page 30), complete the following steps:

- **To Close a Study:**
  1. On the SCRRTF, select the study number from the drop down list. The “Study Title” will auto-populate.
  2. Select the “Name of Local IRB” from the drop down menu and the “Institution’s FWA Number” and the “Local IRB Registration Number” will auto-populate.
  3. Click on the box for closure of study and check the boxes to indicate that each condition is met.
  4. Skip over transfer box.
  5. Click the “Save & Continue” button at the bottom of the form.
  6. You will be taken to a Confirmation and Submission page to verify information as illustrated in Figure 9, page 31. If changes are required,
click the “Go Back” button to make correction. If the information is correct, click the “Submit” button.
7. You will receive an automatic acknowledgment of receipt of your submission.
8. Within 10 days you will receive an email from the CIRB Operations Office confirming closure of the study.

- To Transfer a Study:
  1. On the SCRRTF, select the study number from the drop down list. The “Study Title” will auto-populate.
  2. Select the “Name of Local IRB” from the drop down menu and the “Institution’s FWA Number” and the “Local IRB Registration Number” will auto-populate.
  3. Skip over close box.
  4. Click on the box for transfer of review responsibility and upload a copy of your full board IRB approval letter.
  5. Click the “Save & Continue” button at the bottom of the form.
  6. You will be taken to a Confirmation and Submission page to verify information as illustrated in Figure 9, page 31. If changes are required, click the “Go Back” button to make correction. If the information is correct, click the “Submit” button.
  7. You will receive an automatic acknowledgment of receipt of your submission.
  8. Within 10 days you will either receive an email confirming that the transfer has been completed or you will be contacted by the CIRB Operations Office to answer any remaining questions. Once any questions have been answered, the email confirming completion of the transfer will be sent.
  9. Once the transfer process has been completed, the local IRB has full responsibility for review of the study at their site.
Figure 8 – Study Closure or Review Responsibility Transfer Form (SCRRTF)
Confirmation and Submission

Review information on this confirmation page and click "Submit" if information is correct. If changes are required, click "Go Back" and you will be returned to the Study Review Responsibility Transfer Form.

Once you click "Submit", your browser will automatically take you back to the Facilitated Review (FR) Submission Report webpage.

You will immediately receive an email from the CIRB Operations Office acknowledging your transfer request. You will receive a second email within the next 10 days from the CIRB Operations Office notifying you that the transfer has been completed.

Study Number: 

Study Title: 

Name of IRB: Institution IRB

Institution’s FWA Number: FWA00000000

Local IRB Registration Number: IRB000000000

Study participants are not enrolled at a site covered by this IRB.

IRB Approval Letter: Not Applicable

After your review, select the appropriate option below:

If you want to change any information, click on "Go Back" (all information entered will be lost). 

Go Back

OR

If the information is correct, click the “Submit” button. You will receive an email acknowledgement of the transfer request.

Submit

If you have any questions or are having any difficulty completing this form, please call the NCI CIRB Helpdesk at 888-627-3711 or email nciirseconal@emmes.com

User Number: 431176

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9.0 Reports and Communications

9.1 Reports

The CIRB distributes the CIRB Website Postings Summary via email twice monthly to inform participating institution staff of study-specific documents posted to the Participant’s Area of the CIRB Website since the last distribution.

Since the CIRB Website Postings Summary only lists those documents posted since the previous Summary, it does not list all review documents pertaining to a specific review. The study-specific webpages should be visited to obtain all review documents pertaining to a specific review.

Also included in the CIRB Website Postings Summary are CIRB memoranda and notices.

9.2 Communications

9.2.1 CIRB Website

The primary means of communication to relay study-specific information to local IRBs and research staff is via the CIRB Website. The URL for the CIRB Website is: http://www.ncicirb.org. All documents are posted on the restricted-access side of the website, known as the ‘Participant’s Area’. See Section 8.0 for more information about accessing the Participant’s Area of the CIRB Website.

9.2.2 CIRB Helpdesk

The primary objective of the CIRB Helpdesk is to provide a mechanism for institution, IRB, or research staff to ask questions or provide feedback on CIRB processes. The phone number for the CIRB Helpdesk is 1-888-657-3711. The email address for the CIRB Helpdesk is ncicirbcontact@emmes.com.

The CIRB Helpdesk is staffed between the hours of 8:00 AM and 4:00 PM ET on business days with voicemail activated the rest of the time. Generally, questions receive an immediate answer. When necessary, inquiries about specific issues are assigned to the most appropriate CIRB Operations Office staff that is able to provide an informed response. Inquiries to the Helpdesk are tracked through a tracking database to ensure response accuracy and timeliness.

9.2.3 CIRB Website Postings Summary

The twice a month CIRB Website Postings Summary provides a listing of all document posted to the CIRB Website since the previous distribution.

9.2.4 Study-Specific Notifications

When study-specific notifications are required, the CIRB broadcasts emails to the appropriate stakeholders.
9.2.5 Presentations about CIRB Initiative

The CIRB Operations Office provides information in the form of presentations or a booth at Cooperative Group or other meetings, upon request.

9.2.6 CIRB Local Site Advisory Panel (LSAP)

The Local Site Advisory Panel is composed of 10-12 volunteers that represent CIRB enrolled institutions. The Panel provides feedback on changes and/or updates to current CIRB policies and procedures. The LSAP may also be used as a sounding board for proposed changes to the CIRB policies or procedures prior to implementation.

9.3 CIRB Assistance With Response to Cooperative Group Audits For Studies Under the CIRB

Amendments are CIRB-approved when distributed by the Cooperative Group, therefore, regulatory audit deficiencies related to amendment approvals have not occurred. The CIRB conducts annual continuing review several months before the study expires to allow time for the approval to be posted and used by local IRBs. The CIRB is unaware of any audit deficiencies related to continuing review.

In spite of the above safeguards, there are occasionally misunderstandings or questions that result in an IRB deficiency at time of audit. If your site has received an IRB deficiency pertaining to a study for which your IRB has submitted a Facilitated Review Acceptance Form, the CIRB Operations Office staff will assist the research staff with the response to the deficiency. Notify the CIRB Helpdesk as quickly as possible and attach a copy of the IRB section of the audit report to the email. The CIRB will provide a response addressing the deficiency, including a remediation plan if necessary. The CIRB will address its response to the investigator identified in the audit report. Institutional personnel, as identified by the institution, will be copied on the correspondence, if requested. If a remediation plan was presented in the response letter, it will be immediately implemented by the CIRB.
Appendices

Appendix 1: List of Referenced URLs

http://deainfo.nci.nih.gov/advisory/bsa/bsa_program/bsactprgmin.pdf

SACHRP Letter to HHS Secretary (September 18, 2008)
http://www.hhs.gov/ohrp/sachrp/sachrpletter091808.html

http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm

Food and Drug Administration, (January 2009). Adverse Event Reporting to IRBs – Improving Human Subject Protection

OHRP Guidance, (July 21, 2000). IRB Knowledge of Local Research Context
http://www.hhs.gov/ohrp/policy/local.html

OHRP Guidance, (January 15, 2007). Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

NIH Guidance, (June 11, 1999). Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials

CIRB Website Homepage
http://www.ncicirb.org

Participant’s Area of the CIRB Website
http://www.ncicirb.org/CIRB_Login.asp

Division of Responsibilities between the Central IRB and Enrolled Local Institutions
http://www.ncicirb.org/Division%20of%20Responsibility.pdf

CIRB Member Roster
http://www.ncicirb.org/cirb_roster_brief.asp

CIRB Standard Operating Procedures
http://www.ncicirb.org/CIRB_SOPs.pdf

CIRB: How to Join?
http://www.ncicirb.org/CIRB_Join.asp

CIRB Enrollment Packet
http://www.ncicirb.org/CIRB_Enrollment_Packet.asp

NCI CIRB Institution Enrollment Worksheet
http://www.ncicirb.org/NCI_CIRB_Enrollment_Worksheet.doc

NCI CIRB Authorization Agreement

Checklist for Incorporating the CIRB into your Institution
http://www.ncicirb.org/CIRB%20Checklist_1.13.09.doc

Sample SOP for Utilizing the NCI CIRB
http://www.ncicirb.org/Sample%20SOP%20for%20Utilizing%20the%20NCI%20CIRB%20-%2020090225.doc
Appendix 2: CIRB Operations Office Contact Information and Personnel Listing

Contact Information

Helpdesk Email: ncicirbcontact@emmes.com
Toll Free Number: 1-888-657-3711

NCI CIRB Operations Office
c/o The EMMES Corporation
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Rockville, Maryland, 20850

NCI CIRB Operations Office Staff

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3. Jennifer Dugan, Project Manager
4. John Horigan, CIRB Administrator
5. Laura Covington, QA Manager
6. Birdena Samuel, QA Specialist
7. Andrew O’Connor, CIRB Adult Coordinator
8. Amanda Putnick, CIRB Adult Coordinator
9. Angela Norman, CIRB Pediatric Coordinator
10. LaTisa Hernandez, CIRB Local Context Coordinator
11. John Morais, CIRB Local Context Coordinator
12. Jennifer Berghers, CIRB ICD Specialist/Board Support
13. Diana Orr, CIRB Outreach Coordinator
14. Chelsea Clark, CIRB Client Services Specialist
15. Allison Peel, CIRB Outreach Specialist
16. Emmett Lauer, CIRB Document Control Specialist
17. Amparo Briggs, CIRB Document Control Specialist
18. Brian Campbell, IT Manager
19. Matthew Beyers, Systems Coordinator & IT Support