



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 1102
National Cancer Institute:
Central Institutional Review Board

Purpose

To specify the University of South Alabama IRB requirements and procedures for conducting research sponsored by National Cancer Institute (NCI) and under the purview of the NCI Central Institutional Review Board (NCI CIRB).

Scope

This standard operating procedure applies to all investigators performing research under the auspices of the University of South Alabama and its affiliated institutions.

Applicability

Use of the CIRB facilitated review mechanism is required to investigators seeking to enroll subjects into adult and pediatric, national, multi-center (Cooperative group) cancer treatment trials.

Policy

University of South Alabama investigators intending to conduct any clinical trial reviewed and approved by the NCI CIRB must utilize the CIRB as the IRB of record for the study. When planning to initiate a NCI sponsored cooperative group trial, consult the [Cancer Trials Support Unit \(CTSU\) website](#) to see if the trial is listed on the menu of CIRB approved trials.

The USA IRB maintains responsibilities for local oversight of performance of CIRB-approved studies. These responsibilities involve ensuring the safe and appropriate performance of the research at its affiliated institutions including, but not limited to:

- ensuring the initial and ongoing qualifications of investigators and research staff
- monitoring protocol compliance
- maintaining compliance with state, local or institutional requirements related to the protection of human subjects
- providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research
- investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance.

Procedures

USA investigators planning to conduct a study for which NCI CIRB serves as the IRB of record must receive USA IRB preliminary review and approval to ensure compliance with institutional requirements that are **not** evaluated by the CIRB's local subcommittee. The USA IRB review will be initiated by the IRB staff.

1.0 Submission to USA IRB: Preliminary Review

When an investigator wishes to open a Cooperative Group clinical trial the following steps must be followed:

- 1.1 Create a New Project in IRBNet
- 1.2 Complete USA IRB Part A Application
- 1.3 Complete IRB External Request Review Form
- 1.4 PI must electronically sign package 1 for USA IRB local review
- 1.5 All key personnel listed on Part A IRB application must have completed the required training. See [Human Subjects Training website](#)
- 1.6 Submit documents for **USA IRB** pre-preview and acknowledgment, to include:
 - 1.6.1 Copy of protocol
 - 1.6.2 Consent/assent template(s) provided by NCI CIRB. Include USA IRB – NCI CIRB boilerplate language, as applicable.
The documents listed above in 1.6.1 and 1.6.2 can be obtained from the [CTSU website](#)
 - 1.6.3 Separate HIPAA and/or GINA language per USA IRB – NCI CIRB boilerplate language as applicable.
- 1.7 USA IRB Acknowledgment Letter will be published in Package 1 stating confirmation of NCI CIRB of Record or a decision document stating that the study does not qualify and further guidance provided.

2.0 USA IRB Local Context Language

The USA IRB Local Context Language must be inserted in the NCI CIRB-approved model consent template to create the consent form to use for USA site specific study. (See Informed Consent boilerplate template for NCI CIRB submission)

3.0 What Happens After Submission to the USA IRB?

3.1 After the USA IRB application and required documentation is submitted in IRBNet, it is reviewed by the USA IRB Office to ensure that:

- Institutional requirements for reliance are met, such as training and absence of conflict of interest issues.
- Consent documents use the current CIRB-approved template and the applicable required [USA IRB local context language](#). Compliance with HIPAA regulations are considered an institutional requirement and remain the purview of the local institution. The NCI CIRB does not permit HIPAA language to be included as boilerplate language. HIPAA requirements must be addressed by the institution in a separate document.

3.2 If revisions are needed, the IRBNet package will be unlocked with instructions to complete/revise submission. NOTE: “Mark Revisions Complete” must be selected to notify the IRB that the project is ready for review.

3.3 After all revisions are complete, and the IRB is notified, the study team will receive IRBNet notification of the USA IRB Acknowledgment Letter. The board action document is located in IRBNet under “Reviews” when the study title is selected stating the study is eligible for reliance on the NCI CIRB.

3.4 The USA IRB may determine that a study cannot be conducted, or submitted to the NCI CIRB. In these instances, a decision document will be provided with further guidance.

3.5 The USA IRB will assign the date of acknowledgement as the approval date with a next report due date scheduled in one year. An annual check-in to confirm study remains ongoing or closed must be submitted to the USA IRB. A 60 and 30 day email IRBNet notification will be provided to the study site.

4.0 Obtaining NCI CIRB Approval to Conduct a Study

4.1 Once the study team has received USA IRB acknowledgment in IRBNet confirming that IRB review can be ceded to the NCI CIRB, the USA principal investigator or designee must submit a Study-Specific Worksheet to the NCI CIRB to obtain approval to conduct the study at the University of South Alabama. **NOTE:** Do not submit a

Study-Specific Worksheet prior to receiving USA IRB acknowledgment that a study can be ceded to the NCI CIRB.

- 4.2 Principal Investigator or designee completes the Study-Specific Worksheet which serves as the institution's request to open a study overseen by NCI CIRB. The Study-Specific Worksheet is completed and submitted online in the NCI CIRB's IRBManager system following the NCI CIRB Instruction Manual for Worksheet Completion in IRBManager (on the [CIRB website](#)). Questions about this process should be directed to the NCI CIRB Helpdesk.

ATTENTION !: If someone other than the Principal Investigator submits the Study-Specific Worksheet, IRBManager will automatically generate an email to the Investigator requesting review, confirm intent to comply, and submission of the Worksheet in IRBManager. The Investigator must click the SUBMIT button on the final page or the form will not be submitted.

- 4.3 Once the NCI CIRB has approved the study for conduct at USA, the NCI CIRB is the IRB of record for the study and is responsible for local site issues as well as study-wide oversight. This means:
 - 4.3.1 Study teams must monitor the CTSU website and web-posting summary emails for NCI CIRB approval of amendments and other IRB actions for the study.
 - 4.3.2 Any locally-occurring reportable events must be reported to the NCI CIRB via IRB Manager, following the NCI CIRB Instruction Manual for Worksheet Completion in IRB Manager.
 - 4.3.3 Study teams must comply with all other NCI CIRB requirements, as described in the [NCI CIRB's Standard Operating Procedures](#) and any other CIRB directives.
- 4.4 The Investigator for the study must have an NCI CIRB "Annual Principal Investigator Worksheet About Local Context" on file with the CIRB prior to submitting a new study.
 - 4.4.1 When the Investigator submits the Annual Principal Investigator Worksheet About the Local Context to the CIRB, it is reviewed by the NCI CIRB's Local Context Subcommittee. This subcommittee determines if the Worksheet is acceptable and the Investigators is eligible to conduct studies under the NCI CIRB's oversight.
 - 4.4.2 Both an Annual Principal Investigator Worksheet and a Study-Specific Principal Investigator Worksheet must be approved by the NCI CIRB before a study may be conducted.

NOTE: Research Involving Children: The NCI CIRB will make the determination whether **assent** of the child is required. Procedures for obtaining and documenting assent should follow the USA IRB policies and procedures outlined in *SOP 703: Informed Consent: Research Involving Children*

5.0 NCI CIRB Approval to the Institution

Once the NCI CIRB Local Context Subcommittee approves the Worksheet, the CIRB Operations Office generates the Approval Letter.

NOTE: The applicable USA IRB local context language (Informed Consent boilerplate template for NCI CIRB Submission) must be inserted in the USA site-specific consent form. The approved NCI CIRB study-specific consent model must be utilized.

Responsibilities

1.0 NCI CIRB

- 1.1 Conduct initial reviews of new protocols, discuss any issues with the lead organization and Study Chair, and make a final decision of approval or disapproval of the protocol.
- 1.2 Maintain and make accessible to a designated local IRB at the local institution the CIRB application, protocol reviews, letters to Study Chairs, approvals and disapprovals, and minutes of the CIRB meetings.
- 1.3 Conduct Continuing Reviews, reviews of Serious Adverse Events, protocol amendments, DSMB reports, and any other documents submitted by the lead organization or Study Chair.
- 1.4 Notify each local institution that has accepted the CIRB review of any new materials that have been reviewed for an active protocol and any changes in the protocol approval status.
- 1.5 Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CFR 56 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of each protocol.
- 1.6 Make available to the local institution the roster of CIRB membership and the CIRB Standard Operating Policies and Procedures.
- 1.7 Notify the local institution if there is a suspension or restriction of the CIRB's authorization to review protocols.
- 1.8 Notify the local institution of any CIRB policy decisions or regulatory matters that might affect the institution's reliance on CIRB reviews or performance of the research at the local institution.

2.0 Investigator / Research Site

- 2.1 One individual will be designated from the adult oncology and pediatric oncology research site to add PIs to CIRB's roster using the Roster Update Maintenance System (RUMS).
- 2.2 Principal Investigator must complete [Annual Principal Investigator Worksheet](#). NCI CIRB provides notification.
- 2.3 Study site must inform the IRB of new Investigator/personnel added in CTEP portal.
- 2.4 Complete Change of PI Worksheet, as applicable. This allows multiple studies to be changed to a new PI as part of a single submission
- 2.5 Provide updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is no longer the responsible party for a study under the purview of the NCI CIRB.
- 2.6 Maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy.
- 2.4 After NCI CIRB initial approval, in addition to NCI IRB notification, notification must be provided to the USA IRB for the following actions by creating and submitting a new Package in IRBNet:
 - Annual Check-In Form (USA IRB will prompt via IRBNet email an annual notification referenced as 'next report due date' to serve as an annual check-in for reporting on status of project and remind study team of their responsibilities.)
 - Subject complaints
 - Change in PI/key personnel
 - USA IRB application Part A must be updated, as needed
 - Conflict of Interest updates
 - Breaches of confidentiality
 - HIPAA Privacy and/or Security violations
 - Study suspensions/terminations from NCI CIRB or Sponsor
 - Study closure, submit a study closure report in IRBNet
- 2.5 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.

3.0 USA IRB

- 3.1 In collaboration with the Office of Research Compliance and Assurance, initiate and update the institution's Annual Signatory Institution Worksheet approved by NCI CIRB.
- 3.2 Signatory Institution Primary Contact (IRB Office)

- 3.3 The IRB Office will list studies approved by the USA IRB under the pre-authorization on the upcoming IRB agenda in the “External IRB” section.
- 3.4 To ensure the safe and appropriate performance of the research at its institution, NCI CIRB approved studies include monitoring protocol compliance. The USA IRB/ Office of Research Compliance and Assurance may monitor any NCI CIRB approved protocol as part of its quality assurance program. The CIRB retains the authority to direct the USA IRB to perform such inspections as necessary to assure adequate regulatory compliance.
- 3.5 Notify NCI CIRB immediately if there is a suspension or restriction of a local Investigator
- 3.6 Provide to the CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the local IRB, such as the local IRB administrator. The IRB will update the RUMS Roster required by NCI CIRB.
- 3.7 Record keeping procedures for all files must be established, and NCI CIRB documents, e-mail notifications, and other correspondence must be stored / filed as previously maintained through normal USA IRB approval.
- 3.8 The NCI CIRB is **not** constituted to review the following research listed below. Therefore, the USA IRB will conduct full board review of any study:
 - 3.81 Enrolling Prisoners or have been notified that an enrolled subjects has been incarcerated per 45 CFR 46 Subpart C. Submission of a study for full board review by the USA IRB must follow the procedures outlined in *SOP 903: Research Involving Prisoners*.
 - 3.82 Research conducted under the exception to the requirement for informed consent for emergency research outlined in FD 21 CFR 50.24
 - 3.83 Reports of emergency use of a test article as outlined in 21 CFR 56.102(d), 56.104(c) and 312.36 or the use of a test article without consent outlined in 21 CFR 50.23
 - 3.84 HIPAA authorization language or requests for HIPAA waivers
 - 3.85 Transnational research

Regulated Documentation

21 CFR 56.113; 45 CFR 46.113

University Related Documents

[IRB Registration/Reliance Request Form](#)

[USA IRB Local Context Language – Boilerplate template for NCI Submissions](#)

[SOP 703: Informed Consent: Research Involving Children](#)

[SOP: 903: Research Involving Prisoners](#)

References

[National Cancer Institute Central Institutional Review Board](#)

History:

Effective Date: October, 2018

Revised Date: February, 2019

Responsible Office:

Office of Research Compliance and Assurance