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 rehTj0.n/ to investigators seeking to enroll subjects into adult and pediatric, national, multi-center (Cooperative group) cancer treatment trials.

Policy

2.0 USA IRB Local Context Language

Currently, there is no USA IRB language to be inserted into a CIRB consent or assent form. However, specific HIPAA and GINA language is required as a separate stand-alone document that is presented to the subject during the consent process. The USA IRB will review, approve and stamp these documents.

3.0 What Happens After Submission to the USA IRB?

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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 !

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.

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
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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.

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