



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 1103
External Institutional Review Board(s)

Purpose

The University of South Alabama (USA) Human Subject's Protection Program ensures the safe and ethical conduct of all human subject research conducted at the University and its affiliated institutions. This document sets forth USA policies for the use of external IRBs and summarizes USA IRB responsibilities within these agreements. The document also provides details of USA's IRB processes for meeting its duties to review requests for the use of external institutional review boards.

Policy

The USA IRB authorizes the use of a designated external IRB through an administrative review. The external IRB agrees to take the responsibility of IRB oversight and perform IRB functions in compliance with applicable federal and state regulations for new research studies conducted at USA. The USA IRB conducts an **Administrative Review** of studies requesting use of external IRB oversight.

USA Institutional Review Board

- Once the USA IRB has accepted administrative review for a study, the IRB will acknowledge the external IRB as the IRB of Record for the research study to be conducted at USA.
- The responsibilities identified for local IRBs in the agreement will be met and duplication of effort between the USA IRB and external IRB will be eliminated as far as is consistent with comprehensive protection of human participant safety and welfare.

- The local IRB (USA IRB) will retain certain responsibilities for oversight and review of the research in order to comply with USA requirements, and all pertinent federal, state and local laws and regulations.
- Institutional policies will apply for disclosing financial conflicts of interest.
- Regulatory review and approval will be conducted by the USA Institutional Biosafety Committee and Radiation Safety Committee, as necessary.

USA IRB Responsibilities

The USA IRB is the local institution ensuring the safe and appropriate conduct of the research at USA. This includes, but is not limited to:

- Oversee requirements for human subjects training
- Monitor protocol compliance as part of its quality assurance program
- Changes in conflict of interest
- Change in PI and key personnel
- Managing any serious adverse events occurring at the institution
- Providing a mechanism by which complaints about the research can be made by local study participants or others.

USA has specific responsibilities of the local institution in relation to HIPAA, Informed Consent and Assent, and the reporting of unanticipated problems and serious adverse events, as well as participation by prisoners and individuals with impaired decision making capacity. These have been incorporated into the USA IRB administrative review process and procedures described below, and the guidelines which follow.

The USA IRB Administrative Review Process

The USA IRB administrative review process is designed to simplify local review and approval of trials requesting external IRB oversight. In addition to the initial administrative review process, the USA IRB will also initiate an annual follow-up to check on the status of the study and changes to key personnel. Since the external IRB is accountable for all continuing reviews, the USA IRB is no longer required to conduct reviews of amendments; continuing reviews; reviews of recruitment or educational materials intended for use by current or potential study participants; and review of adverse events.

Procedures

Administrative Review

- The submission materials, together with all appropriate documents relating to the request, will be reviewed by the USA IRB administrative staff and others as applicable. Should the IRB consider administrative review inappropriate for the study (for example, for reasons of risk), the PI will be advised and may submit the study for Full Board Review, using appropriate approved materials.
- Full Board Review by the USA IRB always required if Investigators wish to conduct the following:
 - Enroll prisoners on any trials
 - Planned emergency research
 - Single patient emergency use or compassionate use situations
 - Investigator-initiated studies
 - Phase I or combined Phase I/Phase II trials
 - Gene therapy trials

Western IRB (WIRB®)

The Western Institutional Review Board is an independent central IRB. The USA IRB has implemented processes to carry out **Administrative Review** of designated industry-sponsored clinical trials. This process is initiated by completion of the USA IRB form entitled “*IRB External Review Request Form*”. These processes are detailed in *IRB SOP 1101: Western IRB*. For a comprehensive list of documents and instructions required to proceed with WIRB submission, please visit the USA IRB website [here](#).

Reporting Unanticipated Problems

WIRB agrees to assume IRB oversight responsibility and to perform monitoring of unanticipated problems involving risks to subjects or others; and maintenance of required IRB records pursuant to 21 CFR § 56.115 and 45 CFR § 46.115.

National Cancer Institute’s Central Institutional Review Board (NCI CIRB)

In special circumstances, the USA IRB will carry out administrative review of certain NCI-sponsored Cooperative Group research studies approved by the CIRB, and once the IRB is satisfied that all local context issues have been met, may recognize the CIRB as the IRB of Record for the study at USA and its affiliated institutions. The CIRB’s primary responsibility is initial and continuing review of these research studies. The USA IRB retains responsibilities for local oversight and review of the performance of the research after acceptance of administrative review, and assuring that key personnel credentials are met.

Reporting Unanticipated Problems

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

University Related Documents

[USA Human Subjects Website: WIRB Submission](#)

[USA Human Subjects Website: NCI CIRB Submission](#)

[USA Human Subjects Website: Single IRB](#)

[IRB SOP 1101: Western IRB](#)

Related Forms:

IRB External Review Request Form (Located in IRBNet forms and templates)

References

Western Institutional Review Board Website

The comprehensive WIRB® website for all documentation relating to the WIRB®s reviewed and approved is as follows <http://www.wirb.com/Pages/default.aspx>.

National Cancer Institute Central Institutional Review Board Website

The National Cancer Institute Central Institutional Review Board website can be found at <https://ncicirb.org>.

History:

Effective Date: July, 2017

Revisions:

Responsible Office:

Office of Research Compliance and Assurance