UNIVERSITY OF SOUTH ALABAMA

IRB SOP 1101
Western IRB (WIRB)

Purpose

To specify the University of South Alabama IRB requirements and procedures for reliance on the Western Institutional Review Board (WIRB) as the IRB of record.

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 WIRB facilitated review mechanism is available to investigators seeking to enroll subjects into trials that meet the requirements of this policy.

Policy

University of South Alabama investigators may utilize the WIRB as the IRB of record for specified studies.

The USA IRB maintains responsibilities for local oversight of performance of WIRB-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 WIRB 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.

The criteria for studies from USA investigators to be ***eligible*** for review by WIRB include:

- Research meets the NIH definition of a clinical trial. "A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)"
- Research is a Phase II / III / IV clinical trial
- Protocol must be written and designed by sponsor (not Investigator-initiated)
- The sponsor is a for-profit entity or company
- The sponsor holds all INDs / IDEs
- The research has not previously been submitted to the USA IRB for review.

Studies which involve any of the following are ***not eligible*** for submission to WIRB:

- Phase I Studies (including I/II, studies)
- Planned emergency research
- Single patient emergency use or compassionate use situations
- Embryonic stem cell or gene therapy research
- Protocols funded by a Cooperative Oncology Group/NCI sponsored trials
- Federally funded protocols
- I n vestigator-initiated research
- Industry sponsor that refuses to pay WIRB fees and/or the USA IRB fees
- Research involving prisoners

USA may also require dual review by the USA IRB when the institution deems that the rights and welfare of subjects would be better served by local review.

Submission for WIRB review signifies that:

- WIRB becomes the IRB of Record for the research and is responsible for continuing review as well as review of subsequent amendments and serious adverse events (SAE) as notified by the Principal Investigator and/or the Sponsor.

- The USA IRB is responsible for local context and oversight, including the review of:

    - Amendments affecting changes in local research personnel.
    - Updating USA IRB local context language and HIPAA Authorization template (to be inserted in consent document, as applicable). WIRB will review USA IRB consent language requirements as part of the approval process. Discrepancies will be reported to the USA IRB.

Sponsors are responsible for paying WIRB fees. Sponsors are also responsible for paying a one-time administrative fee to USA IRB for its institutional oversight functions.

Procedures

USA investigators planning to conduct a study for which WIRB 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 WIRB's local subcommittee. The USA IRB preliminary review will be initiated by the IRB staff.

1.0 Submission to USA IRB: Preliminary Review

When an investigator wishes to register a trial that qualifies for WIRB review 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 Review Request Form
1.4 Protocol
1.5 PI must electronically sign package 1 for USA IRB local review
1.6 All key personnel listed on Part A IRB application must have completed the required training. See Human Subjects Training website
1.7 Submit the protocol for **USA IRB** pre-preview and acknowledgment
1.8 USA IRB Acknowledgment Letter will be published in Package 1 stating confirmation of WIRB 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 model consent template to create the consent form to use for USA site-specific study. Site should insert the local language prior to submitting to WIRB for approval.

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.
- Compliance with **HIPAA** regulations are considered an institutional requirement and remain the purview of the local institution. The USA IRB requires the inclusion of HIPAA Authorization as part of the WIRB approved boilerplate language in the consent form, as the WIRB does not function as Privacy Board.

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 any revisions are complete, 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 WIRB.

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

3.5 The USA IRB will assign the date of acknowledgement as the next scheduled annual check-in to confirm study remains ongoing or closed. A 60 and 30 day email IRBNet notification will be provided to the study site.

3.6 USA IRB submission requirements after WIRB initial approval are as follows:

The research site must notify the USA IRB of the following occurrences related to protocols overseen by WIRB:

- Protocol deviations that may represent a systematic problem requiring local evaluation by USA IRB to determine that sufficient local resources are available for safe conduct of the study
- Study holds or suspensions that are not built into the study design from CIRB or Sponsor (eg: interim analysis or enrollment complete need not be reported)
- Study Closure
- Study Terminations from CIRB or sponsor
- Subject complaints
- Conflict of interest updates
- Breach of confidentiality/ HIPAA privacy or security violations
- Amendment to change PI or key personnel (**NOTE: IRB Application Part A must be updated to reflect personnel changes)**
- Completion of annual check-in form (USA IRB – IRBNet email notification will be generated)

4.0 Submission to WIRB

WIRB has partnered with IRBNet, therefore the online submission portal will remain the same as that of the USA IRB. Instructions on submitting your packet are available from the WIRB website. (Access the WIRB Submission Forms)

4.1 WIRB must be selected from the drop down menu and the WIRB link to the forms menu should be accessed to obtain the appropriate submission forms.

4.2 WIRB standard submission requirements include:

4.2.1 Current WIRB initial review submission form
4.2.2 Consent form
4.2.3 PI's current professional license (unless already on file)
4.2.4 PI's CV (unless already on file)
4.2.5 Site- specific material such as subject's material and advertisements.

NOTE: The USA IRB Acknowledgment Letter must be included with your WIRB submission

Create Package 2 to submit documents for WIRB initial review.

DO NOT submit to WIRB until USA IRB preliminary review is complete and acknowledgement letter published.

5.0 Continuing Review

5.1 The investigator will receive email alerts from WIRB regarding the need for continuing review of WIRB approved protocols.

5.2 Prior to the expiration of WIRB approval, the investigator must seek continuing review approval or close out the study by submitting a final report. For continuing review or to close the study, the investigator should submit all protocol documents directly to WIRB following the guidelines provided by WIRB.

5.3 WIRB will contact the investigator with questions about the submission after receipt. WIRB will send all approved documents directly to the investigator.

6.0 USA IRB Annual Check-In

In the absence of continuing review, USA IRB has implemented an automated email notification via IRBNet requesting an annual check-in to report on status of project and remind the study team of their local responsibilities. IRBNet will generate 60 and 30 day notice of reminders prior to the USA IRB date of acknowledgment. The annual check-in date is recorded as the "next report due date" in IRBNet. The USA IRB Check-In is separate from WIRB's continuing review.

7.0 Amendments

7.1 Amendments to the research should be submitted directly to WIRB. Changes to research personnel and Principal Investigator must be submitted to WIRB ***and*** USA IRB.

7.2 USA IRB requires all individuals who are engaged in the research, including but not limited to, being involved in the conduct, review, or oversight of human subject research, complete the required human subjects training and supplemental training, if applicable. Individuals involved in research using PHI must also complete the HIPAA research training requirement.

7.3 Amendments involving Research Personnel and/or a change in the Principal Investigator, the investigator must update the *USA IRB Application Part A*. This amendment may be submitted to USA IRB concurrently with WIRB submission.

8.0 Unanticipated problems or other events requiring prompt reporting

Unanticipated problems or other events requiring prompt reporting and/or serious or continuing non-compliance that involve the USA research site must be promptly reported to the WIRB following the guidelines provided by WIRB. In addition, prompt reporting to the USA IRB is also required.

9.0 Study Closure

The investigator should submit the WIRB Study Closure Report Form and all required protocol documents directly to WIRB. WIRB will contact the investigator with questions about the submission after receipt. WIRB will send all approved documents directly to the investigator.

10.0 Payment of Fees

10.1 USA Fee: USA charges a one-time fee of $2000 for processing/administrative fee for WCG review of eligible industry sponsored trials to cover the costs of screening, institutional oversight, and coordination with WIRB. Submission of eligible industry sponsored trials for review by the WIRB should include a line item in the clinical trial agreement/study budget for IRB review fees. Payment of these IRB review fees is considered a contractual obligation of the sponsor.

10.2 WIRB Fees: WIRB charges a fee for each review activity. **The fees are paid by the Sponsor directly to WIRB.** The WIRB fee schedule is posted in the IRBNet Library.

NOTE: Fees paid by the Sponsor to WIRB are typically not included in the

negotiated budget between the USA and the industry sponsor, because it is preferred that the sponsor pay WIRB directly.

When the sponsor pays WCG directly, there are no additional fees charged by the USA in affiliation with the WCG fees.

University Related Documents

USA IRB webpage - WIRB submissions

References

WIRB Official Site
WIRB Investigator Handbook A Guide for Researchers
WIRB's forms and templates

History

Effective: July 12, 2017
Revisions: February, 2019

Responsible Party

Office of Research Compliance and Assurance