IRB SOP 1101
WCG IRB (formerly WIRB)

Purpose

The purpose of this policy and procedure is to specify the University of South Alabama IRB requirements and procedures for reliance on the WCG Institutional Review Board (WCG, formerly known as 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 WCG IRB 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 WCG as the IRB of record for specified studies.

The USA IRB maintains responsibilities for local oversight of performance of WCG IRB 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

- 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 co(e)]TJ ( )-3 (3 (en1 423.1 178>Tj /TTt654. Td (n)Tj 0.06 Tc 6.24 0 Td Tj

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2.0 Submission to USA IRB: Preliminary Review

When an investigator wishes to register a trial that qualifies for WCG review the following steps must be followed:

2.1 Create a New Project in IRBNet

2.2 Complete and upload the following in package 1 of the New Project:

- x USA IRB Application Part A
- x IRB External Review Request Form
- x WCG Boilerplate Consent Checklist ensuring that sponsor specific additions to the USA IRB Consent language is noted.
- x Consent form(s) - tracked changes are only needed if the consent template has NEVER been reviewed by WCG
- x Sponsor protocol

2.3 PI must electronically sign package 1 for USA IRB local review

2.4 All key personnel listed on Part A IRB application must have completed the required training. See Human Subjects Training website

A USA IRB Acknowledgment Letter and approved WCG Boilerplate Consent Checklist will be published in Package 1 stating confirmation of WCG as the IRB of Record. Alternatively, a decision document stating that the study does not qualify for WCG submission will be published and further guidance may be provided.

Should modifications to USA's boilerplate consent language be requested by the study sponsor after USA's initial acknowledgement in Package 1, an additional package must be submitted to the USA IRB for review. This package will contain an updated WCG Boilerplate Consent Checklist detailing the requested modifications. Additional USA IRB review and acknowledgment of any local consent language modifications must be completed prior to the site's submission to WCG.

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 WCG approved boilerplate language in the consent form, as the WCG does not function as a Privacy Board.

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

3.3 After any required revisions are complete, the study team will receive IRBNet notification of the USA IRB Acknowledgment Letter of 5800030003>l8oUSA -3 (in) ti (t)5

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 WCG. Submission of eligible industry sponsored trials for review by the WCG 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 WCG Fees: WCG charges a fee for each review activity. The fees are paid by the Sponsor directly to WCG. The WCG fee schedule is posted in IRBNet Forms and Templates, in the WCG Library.

NOTE: Fees paid by the Sponsor to WCG are typically not included in the negotiated budget between the USA and the industry sponsor, because it is preferred that the sponsor pay WCG directly.

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

University Related Guidance

USA IRB webpage - WCG submissions

References

WCG IRB Forms and Templates
WCG Website
WCG IRB Guide for Researchers

History

Effective: July 12, 2017
Revisions: February 2019, February 2021, October 2023, September 2024

Responsible Party

Office of Research Compliance and Assurance