UNIVERSITY OF SOUTH ALABAMA

IRB SOP 1101
WCG IRB (formerly WIRB)

Purpose

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
- 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 WCG 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 WCG include:

- Research meets the NIH definition of a clinical trial: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. "
- Research is a Phase II / III / IV clinical trial
- Research meets the criteria for Full Board review
- 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
- The PI meets USA requirements to serve as the PI on a research study

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

- Phase I Studies (including I/II studies)
- Research meets the criteria for Expedited review
- 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
- Investigator-initiated research
- Protocols where the Principal Investigator holds the IND/IDE
- Industry sponsor that refuses to pay WCG fees and/or the USA IRB fees
- Research involving prisoners
- Research requires a HIPAA Waiver of Authorization from the USA IRB
- Other studies to be determined by the local IRB, such as COVID-19 trials

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 WCG review signifies that:

- WCG 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). WCG 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 WCG 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 WCG 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 WCG's local subcommittee. The USA IRB preliminary review will be initiated by the IRB staff.

NOTE: Studies falling under the purview of the USA Clinical Trials Office (CTO) may utilize WCG IRB or local IRB review dependent on a determination from the CTO Director and/or staff.

1.0 USA IRB Local Context Language for Consent Forms

The USA IRB requires specific language to be inserted in the consent form. Individuals applying for WCG review should utilize USA's WCG Boilerplate Checklist for this purpose. The required language will vary from study to study. The site is required to communicate with the sponsor to determine the applicable language and to seek sponsor approval. Sponsor approval for consent language should be received before submitting to the USA IRB for preliminary review.

The site should ensure that the current consent template is used to insert the Local Context Language. The USA IRB's account manager at WCG should be contacted to obtain the current WCG approved consent template. If WCG does not have an approved consent, then the site should obtain the consent template from the sponsor.

No deletions or modifications can be made to the USA IRB Local Context Language. The sponsor can request additional language. However, the addition cannot duplicate local language. Furthermore, additions can only be inserted before or after local language. Additions cannot be inserted in between local language paragraphs, sentences, etc.

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:
    2.2.1 USA IRB Application Part A

2.2.2 IRB External Review Request Form
2.2.3 WCG Boilerplate Consent Checklist ensuring that sponsor specific additions to the USA IRB Consent language is noted.
2.2.4 Consent form(s) - tracked changes are only needed if the consent template has NEVER been reviewed by WCG
2.2.5 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 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, along with the signed WCG boilerplate checklist. The board action documents are located in IRBNet under "Reviews" when the study title is selected stating the study is eligible for reliance on WCG.

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

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

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

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

- Amendment to change PI or key personnel (**NOTE: IRB Application Part A must be updated to reflect personnel changes)**
- Change in funding
- Change of study title
- Updated local recruitment/advertising materials
- Completion of annual check-in form. The date of expiration through WCG will be different from USA IRB. A renewal must be submitted to both IRBs
- Subject complaints
- Conflict of interest updates
- Breach of confidentiality/ HIPAA privacy or security violations
- 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 WCG or Sponsor (e.g.: interim analysis or enrollment complete need not be reported)
- Study Closure
- Study Terminations from WCG or sponsor
- Unanticipated problems
- Any death of a participant outside of death as a result of progressive cancer

4.0 Submission to WCG

WCG 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 WCG website. (Access the WCG Submission Forms)

USA personnel is prohibited from submitting to WCG until USA IRB preliminary review is complete and a formal acknowledgement letter has been published in IRBNet.

4.1 WCG must be selected from the drop down menu in IRBNet Forms and Templates and the WCG link to the forms menu should be accessed to obtain the appropriate submission forms.

4.2 Create Package 2 to submit documents for WCG initial review. The following documents should be submitted:

4.2.1 Current WCG initial review submission form
4.2.2 PI's current professional license (unless already on file)
4.2.3 PI's CV (unless already on file)
4.2.4 The USA IRB Acknowledgment Letter (from package 1 in IRBNet)
4.2.5 Signed WCG Boilerplate Checklist (from package 1 in IRBNet)
4.2.7 Site- specific material such as subject's material and advertisements.
4.2.8 If the study has never been reviewed by WCG then include:

4.2.8.1 Consent form with track changes
4.2.8.2 Protocol
4.2.8.3 Investigator's Brochure (if applicable)

5.0 Continuing Review

5.1 The investigator / staff will receive email notification with a partially completed renewal form from WCG regarding the need for continuing review of WCG approved protocols.

5.2 Prior to the expiration of WCG 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 WCG following the guidelines provided by WCG.

5.3 WCG will contact the investigator with questions about the submission after receipt. WCG will publish all approved documents in IRBNet.

6.0 USA IRB Annual Check-In

In the absence of continuing review, the USA IRB has implemented an automated email notification via IRBNet requesting an annual check-in to report on the status of projects and remind the study team of their local responsibilities. IRBNet will generate 60 and 30-

day notice of reminders prior to the USA IRB Next Report Due date. The USA IRB Check-In is separate from WCG's continuing review.

7.0 Amendments

7.1 Amendments to the research should be submitted directly to WCG. Changes to research personnel and/or Principal Investigator must be submitted to WCG ***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 WCG 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 WCG following the guidelines provided by WCG. In addition, prompt reporting to the USA IRB is also required.

9.0 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 Documents

USA IRB webpage - WCG submissions

References

WCG Official Site

WCG Investigator Handbook A Guide for Researchers

WCG's forms and templates

History

Effective: July 12, 2017

Revisions: February 2019, February 2021, October 2023

Responsible Party

Office of Research Compliance and Assurance