copernicus group independent review board
A WIRB-Copernicus Group Company

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www.cgirb.com

Copernicus Group Independent Review Board

Frequently Asked Questions – Sponsors and CROs

How will my study team communicate with CGIRB?

CGIRB works intimately with the appropriate study team members to ensure workflow efficiency throughout the review process. From outlining submission requirements to walking through informed consent revisions- our teams remain in constant touch with your organization. Furthermore, you will have access to CGIRB's online document management solution, MyConnexus, to submit, track, and view recently submitted materials to CGIRB.

How do I register for MyConnexus?

To register for MyConnexus please click here, or visit: http://www.connexus.wcgclinical.com.

What should I expect if I need translated consent forms for any of my research sites?

After you submit your translation request to CGIRB, we will coordinate with our partners to produce translated versions of the currently approved English consent forms. English versions of the informed consent documents are reviewed and sent separately from the translated informed consents. Therefore, the translated documents will be received subsequent to the English documents, and will incur an additional translation fee.

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What is CGIRB's policy for reporting IND Safety reports?

The majority of IND Safety Reports, Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports, Council for International Organizations of Medical Sciences (CIOMS) Reports, and MedWatch Reports ("Reports") **are unlikely** to meet reporting requirements under CGIRB reporting guidelines. Reports that **must** be reported are those reports that indicate a new or increased risk of harm to subjects or others. Generally, to be reportable, such an event should be previously unknown to the IRB and requires an action taken to minimize the risk to other subjects, such as a change to the protocol or additional disclosure of risk information in the consent document.

If there is an agreement that the sponsor report unanticipated problems directly to CGIRB on the behalf of the PI, that is the only report that needs to be submitted to CGIRB. If there is no such agreement in place, the PI is required to submit reports to CGIRB, if they are determined to be reportable unanticipated problems.

Submit the report with the completed CGIRB Promptly Reportable Information Form within 5 business days of your receipt.

What information is required when submitting recruitment materials to CGIRB for review?

The CGIRB Change in Research and Subject Recruitment Submission Form (either a "smart form" version or a paper version) should be used to submit recruitment materials for review after initial review of the research. The basic information required includes:

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- Investigator name
- Sponsor/CRO name
- Research protocol number
- Name of the person submitting

Ads must be submitted and approved by CGIRB before they are used.

For expedited results, when submitting subject recruitment materials or other subject materials (diaries, questionnaires, etc.) that have been previously reviewed by CGIRB, state in the cover letter which items have been previously reviewed by CGIRB. Our support staff will provide the Board with information about the previous Board review, and the previous decision of the Board will be taken into account when the additional materials are reviewed.

Recruitment materials should be submitted via Connexus.

When does CGIRB require the Sponsor/CRO to complete the Study Closure Report Form for a particular site?

To allow the Board to review your submission, CGIRB requires that the Study Closure Report Form be submitted at least six to eight weeks prior to study expiration date. You should submit the report only if all of the following have been accomplished:

1. All subjects at your site have finished their final visits and any follow-up activities (such as phone calls, post-card contacts, or long term follow up is required by the protocol) are completed
2. The sponsor or the sponsor representative has indicated that the study is closed at this site
3. If the study was conducted under a Federalwide Assurance, all data analysis at the site is completed.

If the above items have not been completed, please submit a Continuing Review Report.

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At CGIRB, are Investigator Drug Brochures approved?

Federal regulations do not require that IRBs approved Investigator Brochures (IB). However, CGIRB does utilize IBs when considering research for approval. Because the IB is drug-specific, it is reviewed for each research protocol utilizing that drug; yet, the IB itself is not considered for approval or disapproval.

When utilizing a trial undergoing SRS, who do I work with? Do I have a single point of contact?

When employing the SRS process for your study, you will have a single point of contact (POC). At the beginning of the study, your Client Relations Manager will introduce you to your POC who will be with you throughout the lifetime of the study, providing you with stability and efficient management of your clinical trial.