copernicus group independent review board
A WIRB-Copernicus Group Company

5000 CentreGreen Way
Suite 200
Cary, NC 27513
919.465.4310
f/ 919.465.4311
www.cgirb.com

Copernicus Group Independent Review Board

Frequently Asked Questions – Investigators

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.

Is CGIRB registered with the Office of Human Research Protections and FDA?

Yes. Copernicus Group Review Board's IRB registration number with OHRP and FDA is: IRB00001313.

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What should I expect if I need translated consent forms that have been customized to my site?

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.

What is CGIRB's policy regarding the Statement of Investigator, form FDA 1572?

Investigators are not required to submit a 1572 to CGIRB, even when one is required by the FDA for the research being conducted.

Does CGIRB require a Curriculum Vitae (CV) to be submitted on behalf of each sub-investigator?

Curriculum Vitae's (CV) for sub-investigators are not generally required, however, you might be asked to submit a sub-investigator CV if the Board requests additional information about your site. If a sub-investigator CV is submitted, it must be current within two years.

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What does the term "investigator generated research" mean?

Under FDA regulations, investigator generated research is when the principal investigator is acting as both the sponsor and the investigator. Under this definition, the principal investigator initiates and conducts the research. When submitting investigator generated research to CGIRB, you should submit all of the necessary paperwork at both the study-level and site-level.

For a trial involving pediatrics, do the parents need to sign the consent form in addition to the child?

Parents are not required to sign the assent form that is signed by the child.

The regulations require a signed permission form from the parents of pediatric subjects when the research involves more than minimal risk. CGIRB generally reviews a separate Parental Permission form for nearly all research studies involving children, regardless of the risk determination.

As part of the initial review process, CGIRB determines whether the permission of one parent or both parents is appropriate for a study, which is also communicated to the sponsor as part of the initial review.

Does CGIRB provide a template for the California Experimental Subject's Bill of Rights?

Yes, CGIRB does provide a copy of the California Bill of Rights template. This template is accessible for download on our forms page.

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The "Protection of Human Subjects in Medical Experimentation Act" and California Health and Safety Code for the state of California requires that the California Experimental Subject's be given to research participants before conducting the initial protocol consent process. This document is required to be signed and dated at the time of initial consent.

How does CGIRB differentiate "compensation" versus "reimbursement"?

According to regulations, the term "compensation" refers to payment to a volunteer for his/her participation in a research study. Meanwhile, the term "reimbursement" refers to gifts for participant retention purposes (i.e. parking and travel expenses), or medical devices retained by the study participant.