



Submission Guidelines for Study Start Up



Below is a list of information and forms to be included in the Copernicus Group Independent Institutional Review Board (CGIRB) submission packet from the sponsor/contract research organization (CRO), institution, site management organization (SMO), or the principal investigator (PI). Forms listed below that are available on this website are noted in ***bold italics***. Please check with your sponsor contact to determine what you need to submit directly to CGIRB. A review cannot be performed prior to the receipt of all appropriate information.

For Protocol Submissions:

- ***Submission Letter for CGIRB Review***
- Final signed protocol
- Proposed ***Subject Information and Consent Form and Authorization to Use and Disclose Personal Health Information for Research Template*** (must be in Microsoft Word format on CD or electronically)
- Clinical Investigator's Brochure (CIB) or Package Insert, when applicable. Please provide the Package Insert or Product information (or a link to this information online) for any comparator agents for which risks are included in the proposed informed consent form.
- Proposed advertisement/recruitment material
- ***Study Application Form***
- ***Indemnification Agreement*** signed by sponsor

For New Investigator Submissions:

- ***Investigator Site Questionnaire*** (Complete the ***Investigator Site Questionnaire for Additional Sites*** for each site where research will be conducted)
- Current curriculum vitae (CV) of PI. CVs must verify affiliation to at least one study site and must be current within 2 years.
- Sub-investigator CVs are not generally required to be submitted, but if provided must be also current within 2 years. If the PI is not an MD and the study requires an MD, one of the sub-investigators must be an MD.
- Current professional license of PI. If PI is licensed in Massachusetts, a copy of the research license must also be included.
- Proposed site-specific advertisement/recruitment material and site-specific requirements for the subject information and consent form (including any state and/or local requirements that are stricter than the Federal requirements).
- Any additional study-related documentation to be provided to the subject (eg, diaries).

All submission documents should be sent as individual files to avoid processing delays.

Collect all requested information and e-mail, fax, or mail to the following address, or submit via Intralinks or **CGIRB Connexus®, so that it is received at CGIRB by your selected submission deadline.**

Incomplete packets or packets received after the submission deadline published on the CGIRB web site (www.cgirb.com) will be placed on a later meeting agenda.

Copernicus Group IRB One Triangle Drive, Suite 100 PO Box 110605 Research Triangle Park, North Carolina 27709	Fax: (919) 465-4311 irb@cgirb.com Subject Line - Attn: IRB Services
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CGIRB sends all original correspondence to the PI. Upon written request, CGIRB will provide a copy of the approval documentation directly to the sponsor, CRO, institution, or site management organization (SMO) managing the study. The PI is responsible for providing documents requested by all other parties. When items have been previously approved by CGIRB (and are not submitted with a New PI submission), it is up to the sponsor/CRO/institution/SMO to provide copies of these approved items to the sites.