



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, 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**
- Study Protocol (final version)
- 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 disk and 1 hard copy unless submitted electronically)
- Clinical Investigator's Brochure (CIB) or Package Insert
- Proposed advertisement/recruitment material
- **Study Information and Commitment Form**
- **Indemnification Agreement** signed by sponsor

For New Investigator Submissions:

- Copy of completed and signed Form FDA 1572 - Maintain the original at your site. (*Please ensure that all sections (1-11) are completed as any blank sections will result in review delay.*)
- **Investigator Site Questionnaire** (Complete the **Investigator Site Questionnaire for Additional Sites** for each site listed in Section 3 of Form FDA 1572.)
- Current curriculum vitae (CV) of PI. CVs must verify affiliation to at least one study site and must be current within 2 years.
- 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).

Collect all requested information and e-mail, fax, or mail to the following address, or submit via Intralinks, 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
Attention: IRB Services
Fax: (919) 465-4311
irb@cgirb.com

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 to provide copies of these approved items to the sites.