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|   | <h1>Submission Letter for CGIRB Review</h1> | <p>Internal Use</p> |
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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

RE: Protocol # and Title: _____
Sponsor: _____

Dear Copernicus Group IRB:

I am requesting that the above-referenced research submission be reviewed by the Copernicus Group Independent Institutional Review Board (CGIRB) under the provisions of Title 21 CFR (FDA-regulated research), Title 45 CFR (non-FDA-regulated research), and ICH Good Clinical Practices (GCP) Guidelines.

I understand that initial CGIRB Board review cannot take place until all required documents have been submitted to CGIRB and that the research may not begin prior to IRB review and approval. In accordance with the CGIRB submission checklist below, all necessary forms are complete and are included (note any exceptions).

| SUBMITTED | DOCUMENT LISTING FOR INITIAL REVIEW OF PROTOCOL |
|--------------------------|--|
| <input type="checkbox"/> | Final protocol |
| <input type="checkbox"/> | 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/CD and 1 hard copy unless submitted electronically) |
| <input type="checkbox"/> | Clinical Investigator's Brochure (CIB) or Package Insert |
| <input type="checkbox"/> | Any proposed Advertisements/Recruitment Materials |
| <input type="checkbox"/> | Study Information and Commitment Form |
| <input type="checkbox"/> | Indemnification Agreement signed by sponsor (CGIRB template or sponsor company template) |
| | |
| SUBMITTED | DOCUMENT LISTING FOR REVIEW OF INVESTIGATOR |
| <input type="checkbox"/> | Copy of completed and signed Form FDA 1572 |
| <input type="checkbox"/> | Investigator Site Questionnaire(s) (Complete the Investigator Site Questionnaire for Additional Sites for each site listed in Section 3 of Form FDA 1572) |
| <input type="checkbox"/> | Current CV of PI |
| <input type="checkbox"/> | Copy of current professional license of PI (and a copy of the <u>research license if PI is licensed in Massachusetts</u>) |
| <input type="checkbox"/> | Proposed site-specific advertisement/recruitment material |
| <input type="checkbox"/> | Any additional study-related documentation to be provided to the subject (eg, diaries) |
| | |
| SUBMITTED | DOCUMENT LISTING FOR ONGOING REVIEW |
| <input type="checkbox"/> | Protocol amendment or administrative change |
| <input type="checkbox"/> | Proposed site-specific advertisement/recruitment material |
| <input type="checkbox"/> | IND safety report(s) |
| <input type="checkbox"/> | Site-specific Change Request Form |
| <input type="checkbox"/> | Continuing Review Status Report |
| <input type="checkbox"/> | Investigator Site Closure Request and Final Study Status Report |
| <input type="checkbox"/> | Unanticipated Problem Report Form and Coversheet |

Name and Title of Individual Making Submission

Date