



## Study Information and Commitment Form



Internal Use

**Blank & incomplete answers will result in delayed reviews!**

*Press F1 from any form field for form completion guidance.*

### STUDY # AND TITLE:

Phase of Study:

### SPONSOR INFORMATION

Sponsor Name:	
Address:	
Phone:	Contact Name:
Fax:	E-mail:

### CRO, SMO, OR COORDINATING GROUP INFORMATION

CRO, SMO or Coordinating Group <i>(if applicable)</i> :	
Address:	
Phone:	Contact Name:
Fax:	E-mail:

*The following information is not required for multi-site studies*

### SPONSOR-INVESTIGATOR INFORMATION

Investigator Name:	
Address:	
Phone:	
Fax:	E-mail:

**STUDY INFORMATION**

Anticipated # of CGIRB principal investigators (PIs): _____ Anticipated # of subjects to be enrolled per site: _____	
Month PIs will begin to be submitted: _____	For how many months will PIs be submitted? _____
Total duration of study (first PI submitted through last subject's completion): _____	
Is this study Federally funded? <input type="checkbox"/> Yes <input type="checkbox"/> No	
IND/IDE Number (if applicable): _____	
Has this study been submitted to any other IRB for review prior to submission to Copernicus Group IRB? <input type="checkbox"/> Yes (Attach a detailed explanation) <input type="checkbox"/> No	
How do you ensure each investigator taking part in this study has a comprehensive understanding of GCP as it relates to human subject protection?	
How will you ensure that each investigational site has a proper facility and protocol-required equipment to conduct this research study? _____	
Will you verify that each site has access to the required subject population being studied? _____	
Do you anticipate any IND Safety Reports? <input type="checkbox"/> Yes <input type="checkbox"/> No If so, who will submit these reports to CGIRB? (eg, Sites, sponsor on the behalf of all sites) _____ Please note: CGIRB will immediately review the first uniquely numbered IND Safety Report, whether initial or follow up, submitted for any particular study. After CGIRB's review, an acknowledgment of the IND Safety Report's review will be sent to all active Principal Investigators. If the sponsor elects to submit on the behalf of ALL sites, it is their responsibility to notify the sites NOT to submit these reports to CGIRB.	
Will there be any subject recruitment or advertisements submitted after initial review? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Will you need a translated subject information and consent form document for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No If <b>YES</b> , language(s) (list all that apply)? _____ If <b>YES</b> , will you require English back translation(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No Will you need any additional documents translated such as the Subject Diary, Instructions or Medicine Label? <input type="checkbox"/> Yes <input type="checkbox"/> No Specify: _____ Note: If any PI submits site-specific wording that deviates from the CGIRB-approved <i>Subject Information and Consent Form and Authorization to Use and Disclose Personal Health Information for Research Template (SICF)</i> , an additional fee will be incurred in order to translate that site-specific wording. We especially encourage you to closely examine the payment to subjects section of the SICF and make sure all PIs agree to use the language agreed upon by CGIRB and the sponsor.	
Do you anticipate continuing review for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Are there any other unique qualities about this study?	
Are there adverse events of special interest? <input type="checkbox"/> Yes <input type="checkbox"/> No If <b>YES</b> , describe:	
<b>Additional Requirements:</b> (a) Please attach a copy of the standard language approved for subject compensation for research-related injuries (may be provided in the SICF template). _____ (b) Please attach a copy of the section from the investigator research agreement(s) that outlines the amount of compensation to be paid to research participants.	
<b><i>When items have been previously approved by CGIRB (and are not submitted with a new PI submission), it is up to the sponsor/CRO to provide copies of these approved items to the PIs.</i></b>	

**SHIPPING/BILLING INFORMATION – PI SITES**

**Shipment method for hard-copy approvals:**  
 FedEx  (preferred)      Airborne/DHL       UPS       US Mail

**SHIPPING/BILLING INFORMATION – STUDY CONTACTS**

**Shipment method for hard-copy approvals:**  
 FedEx  (preferred)      Airborne/DHL       UPS       US Mail   
 E-mail PDF       Intralinks

**Shipping Account # to be used for this project:**

**Reference # to be entered on all shipments:**

**Send invoices to the following company/address:**

<b>Accounts Payable contact:</b>	<b>Phone:</b>
----------------------------------	---------------

**Accounts Payable Contact E-mail Address:**

**SPONSOR/CRO OBLIGATIONS**

By signing below, the sponsor/CRO agrees to provide Copernicus Group IRB with Investigators qualified by education, training, and experience to conduct the research project safely and competently. The sponsor/CRO agrees to promptly provide the following information relevant to the protection of human subjects:

1. Reports of any findings from the research that affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter CGIRB approval to continue the study. Such reports include, but are not limited to, data safety monitoring board (DSMB) summaries, reports of unanticipated problems involving risks to subjects or others, and/or findings from regulatory inspections.
2. Information that may directly affect participant safety, medical care, or willingness to continue participation will be communicated to subjects in a timely manner.

**Provide the following with this research submission:**

A written plan for providing medical care and compensation for medical care for research participants who experience a research-related injury during the study (a copy of the relevant section from the master investigator research agreement may be submitted).

---

**Printed Name of Individual Completing Form**

**Printed Title of Individual Completing Form**

---

**Signature**

**Date of Signature**