

 	<h2 style="margin: 0;">Investigator Site Questionnaire for Phase IV, Non-IND, and Device Studies</h2>	<i>Internal Use</i>
--	---	---------------------

**IMPORTANT:** Please type or print clearly. Press F1 from any form field for form completion guidance.

Refer to CGIRB's *Investigator Guidebook* for information regarding investigator responsibilities (located in the forms section of our website at <http://www.cgirb.com/tcg/forms.php>)

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

Protocol #: _____		IRB Tracking #: _____	
Sponsor: _____		<Internal use only>	
Principal Investigator: _____		Study Site Name: _____	
Address: _____			
City: _____	State: _____	Zip: _____	
Phone: _____	Fax: _____	E-mail: _____	
Site Contact Name: _____	Phone: _____ Ext. _____	E-mail: _____	
Will there be any additional sites? <input type="checkbox"/> No <input type="checkbox"/> Yes (If <u>YES</u> , please submit an <a href="http://www.cgirb.com/tcg/forms.php">Investigator Site Questionnaire for Additional Sites</a> for each additional site – <a href="http://www.cgirb.com/tcg/forms.php">http://www.cgirb.com/tcg/forms.php</a> )			

<b>CONTACT NUMBERS FOR SUBJECT USE</b> <i>(Per federal regulations, this information <u>must</u> be included in your site-specific subject information and consent form)</i>
---

Day phone # (Mandatory): \_\_\_\_\_

24-hour phone # (Mandatory): \_\_\_\_\_

<b>SUBJECT COMPENSATION FOR PARTICIPATION IN THE RESEARCH STUDY</b> <i>(This information will be included in your site-specific subject information and consent form)</i>
--

- Subjects will not receive any payment for taking part in this research study.
- For participation subjects will be paid \$\_\_\_\_\_ for each completed visit for a possible total of up to \$\_\_\_\_\_.

**OR**

- Payment for participation varies  
*Attach a separate sheet with site-specific compensation – information provided must be legible*

Are you participating in a sub study under this protocol for which a separate subject information and consent form will be used?  Yes  No

If YES, include information with regard to any compensation that will be paid (attach a separate sheet if necessary). \_\_\_\_\_

**\*Note – CGIRB will compare this information with the contract information provided by the sponsor/CRO.**

**SUBJECT INFORMATION AND CONSENT FORM TRANSLATION**

Will a translated\* version of the subject information and consent form be needed to facilitate a subject's understanding of the research study?  No  Yes

If yes, specify which language(s) are needed: \_\_\_\_\_

**\*Please note that certified translations must be approved by CGIRB prior to use.**

**REGULATORY INFORMATION**

1. Has FDA, OHRP, or another regulatory agency inspected/evaluated the principal investigator or the research site(s) within the past 5 years?  No  Yes

If **YES**, was a Form FDA 483 or other list of observations issued?

No  Yes

(If **YES**, provide a copy of the Form FDA 483/list of observations and response letter)

2. Has the principal investigator or research site(s) ever been issued any of the following?

No  Yes (If **YES**, provide copies of all related documents)

NIDPOE (Notice of Initiation of Disqualification Proceedings and Opportunity to Explain)

Suspension

FDA Warning Letter

3. Have any of the following ever been denied, revoked, suspended, reduced, limited, placed on probation, not renewed, relinquished or subject to disciplinary action? If **YES**, provide copies of all related documents including resolution steps.

a. Research privileges at this site?  No  Yes

b. Medical licensure in any state?  No  Yes

c. Other professional licensure/ registration?  No  Yes

d. Membership on any hospital staff?  No  Yes

e. Clinical privileges?  No  Yes

f. Professional society memberships or fellowship/board certifications?  No  Yes

4. Have any type of professional sanctions, including fines, or DEA prescribing privileges ever been levied against you?

No  Yes (If **YES**, provide copies of all related documents including resolution steps)

5. Has any patient or subject ever made a complaint against the principal investigator, sub-investigator(s), or this research site?

No  Yes (If **YES**, provide copies of all related documents including resolution steps)

6. Is any action or investigation currently pending before any state licensing board, federal agency or court of law concerning the professional conduct of the principal investigator in his capacity as a research investigator or as a clinician?

No  Yes (If **YES**, provide copies of related documentation)

7. Does the principal investigator, sub-investigator(s), or any immediate family member(s) of the aforementioned individuals have a conflict of interest with the study sponsor, sponsor representative(s), or other study-related entities as outlined in the CGIRB *Investigator Guidebook* (<http://www.cgirb.com/tcg/forms.php>)?

No  Yes

(If **YES**, submit a completed *Conflict of Interest Disclosure Form for Investigative Sites* for each individual with conflicting interest.)

**8. Training and qualifications of the principal investigator**

a. Are you and your research staff knowledgeable of Good Clinical Practices (GCP), particularly 21 CFR 312, Subpart D, “Responsibilities of Sponsors and Investigators” or 21 CFR 812, Subpart E “Responsibilities of Investigators” for device studies?

Yes  No (If NO, attach an explanation)

b. What training have you had in the protection of human research subjects:

<input type="checkbox"/>	None
<input type="checkbox"/>	OHRP Training modules
<input type="checkbox"/>	NIH Human Participant Protections Education
<input type="checkbox"/>	Certified Investigator Training Initiative (CITI)
<input type="checkbox"/>	DIA; Certified Clinical investigator (CCI)
<input type="checkbox"/>	SOCRA; Clinical Research Professional (CRP)
<input type="checkbox"/>	ACRP; Certified Clinical Trial Investigator
<input type="checkbox"/>	Other human subject protection training (specify): _____

**9. Experience**

a. How long have you been conducting clinical research? \_\_\_\_\_  years or  months

b. How many studies have you conducted? \_\_\_\_\_

c. What types of studies have you conducted (therapeutic areas)? \_\_\_\_\_ OR  See CV for complete list

d. How many studies are you currently conducting? \_\_\_\_\_ (if more than 16, please answer questions d (i), (ii), (iii), and (iv))

- i. How many studies per clinical research coordinator? \_\_\_\_\_
- ii. What is the average number of subject visits per day? \_\_\_\_\_
- iii. Of the active studies, how many are currently enrolling? \_\_\_\_\_
- iv. Which phase study (Phase I-IV) are most of your active studies? \_\_\_\_\_

e. What percentage of your time is devoted to conducting research? \_\_\_\_\_.

f. State the number of the key study staff that will assist in this research?

- \_\_\_\_\_ Sub-investigators
- \_\_\_\_\_ Clinical Research Coordinators
- \_\_\_\_\_ Pharmacists
- \_\_\_\_\_ Other (eg, laboratory technicians, regulatory specialists)

g. Provide a summary of qualifications for the above-listed study staff (attach a separate sheet, as necessary): \_\_\_\_\_

**RESEARCH SITE AND COMMUNITY INFORMATION**

**10. How would you generally describe your research setting? (Check only one box)**

Rural  Suburban  Urban  Other (describe): \_\_\_\_\_

**11. Setting of the study site:**

Hospital  Research Clinic  Private Practice  Other (describe): \_\_\_\_\_

**12. What are the specific community attitudes towards the conduct of research in your local community that CGIRB should be knowledgeable of prior to reviewing this study for your local site? Check only one.**

Neutral  Positive  Negative (explain): \_\_\_\_\_

13. Are you aware of any state or local laws that would impose stricter or additional requirements than those federally recognized on the subject information and consent form?  No  Yes

If **YES**, provide details:

14. Does a local IRB have jurisdiction over this site?

No  Yes

If **YES**, submit a **Transfer of IRB Obligations Form** (<http://www.cgirb.com/tcg/forms.php>) or equivalent documentation.

15. If you will be conducting the research study at multiple sites, have all the facilities been granted permission for this research to be conducted at their facility? \_\_\_\_\_

16. What is the distance between the nearest hospital and the research site? \_\_\_\_\_

17. Describe the on-site emergency equipment available for the subjects:

Crash Cart  Emergency Meds  CPR certified staff and dial 911  
 Other (describe): \_\_\_\_\_

18. Describe additional resources unrelated to emergency care, if applicable:

Interpreters  Counseling services  Bilingual staff members  
 Other (Specify): \_\_\_\_\_  N/A

**STUDY CONDUCT & SUBJECT INFORMATION AND CONSENT FORM PROCESS**

19. How will subjects be recruited for this study? (check all that apply)

Existing Patients  Referrals  Advertisements\*\*  
 Other (please specify): \_\_\_\_\_

**\*\*All subject recruitment materials must receive CGIRB approval prior to use**

20. Indicate the approximate demographics of your site's anticipated subject population:

a. **Gender** (must total 100%)  
 Male: \_\_\_\_\_% Female: \_\_\_\_\_%

b. **Race/Ethnicity** (must total 100%)  
**For ethnicity guidance visit, <http://www.cgirb.com/tcg/faq.php#ethnicity>**

Asian: _____%	American Indian or Alaska Native: _____%	Native Hawaiian or Pacific Islander: _____%	Other: _____%* (*please specify: _____)
White: _____%	Black or African American: _____%	Hispanic or Latino: _____%	

c. **Are any of the above-listed populations non-English speaking?**  No  Yes  
 Translated documentation and an interpreter are required (see #18)

**21. Do you anticipate recruiting subjects from the following vulnerable populations?**

No       Yes – Check all applicable categories below

**Note: Marking the box beside a vulnerable population indicates your understanding of how to protect that group as outlined**

- a.  **Children:**
  - Assent will be solicited from subjects age 7 and older
  - Investigator will ensure that outside parties (parent/guardian) are not unduly influencing subject to participate
  - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information
- b.  **Adults with Diminished Decision-making Capacity**
  - Assent will be solicited from subjects with limited decision making capacity
  - Investigator will ensure a legally authorized representative is used when appropriate or required by protocol
  - Investigator will ensure that outside parties (caregiver/LAR) are not unduly influencing subject to participate
  - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information
- c.  **Economically Disadvantaged/Unemployed**
  - Low/ moderate/no compensation is provided to eliminate possibility of undue influence due to financial incentive
- d.  **Educationally Disadvantaged**
  - Investigator will ensure the consent document is read to the subject and that an impartial witness is present.
  - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information
- e.  **Visually Impaired/Illiterate**
  - Investigator will ensure the consent document is read to the subject and that an impartial witness is present.
  - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information
- f.  **Limited English skills and/or Non-US Citizens**
  - Subject will be provided with documentation in native language if unable to read English
  - Staff /independent interpreter has ability to interpret subject's native language if unable to comprehend English
  - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information
- g.  **Employees/Colleagues/Students of the Principal Investigator and/or Study Staff**
  - Investigator will ensure & explain that participation does not affect subject's current position
- h.  **Pregnant Women**
  - Possible risks to mother and fetus will be clearly outlined

**22. If question #21 was answered NO, please skip this question.**

**When enrolling vulnerable population(s) from #21, will you meet CGIRB's listed expectations to protect these populations?**     Yes                       No (Attach an explanation)

**23. Will subjects with legally authorized representatives (LAR) or a guardian be enrolled?**

No       Yes

**If YES, how will you verify who constitutes an LAR or a guardian in your state?**

Legal counsel                       Sponsor/CRO                       State law reference material  
 State law codes and statutes                       Other (specify): \_\_\_\_\_

**24. Who typically discusses the subject information and consent form process with the potential subject? (Check all that apply)**

Principal Investigator       Sub-Investigator       Research Coordinator  
 Other (specify): \_\_\_\_\_

**25. Will you or whoever conducts the subject information and consent form process spend as much time as needed to thoroughly explain and respond to any questions the potential subject may have about the study, and allow him/her as much time as needed to consider whether to enroll or not?**

- No (Attach an explanation)  Yes

**26. Will potential subjects or their legally authorized representative be given adequate opportunity to read and consider the consent document before it is signed?**

- No (Attach an explanation)  Yes

**27. How will you maintain the confidentiality of data?**

*Confidentiality* refers to the agreement between the investigator and participant in how data will be managed and used.

- Paper-based records will be kept in a secure location accessible only to study staff
- Computer files will be accessible only to study staff and will be made available through passwords
- Study staff will sign confidentiality agreements regarding the protection of identifiable health information prior to accessing study information
- Other (please specify): \_\_\_\_\_

**28. Please describe provisions to protect the privacy interests of participants.**

*Privacy* refers to persons' interest in controlling the access of others to themselves, such as the ability to control who sees them, hears them, touches them, and has access to their private information. Additional privacy interests include the time and place where subjects provide information, the nature of the information provided by the subjects, the nature of the subjects experiences during the trial, and who receives and can use the information.

**a. Will subjects be consented in a private area away from the public?**

- No (Attach an explanation)  Yes

**b. Will study-related assessments be conducted in a private area?**

- No (Attach an explanation)  Yes

**c. Will the private information collected be limited to what is required by the research?**

- No (Attach an explanation)  Yes

**d. Other than the above, are there additional provisions to protect the privacy of subjects?**

- No  Yes (If **YES**, describe): \_\_\_\_\_

**PRINCIPAL INVESTIGATOR OBLIGATIONS**  
*(MAY ONLY BE COMPLETED BY PRINCIPAL INVESTIGATOR)*

**I attest that, as the principal investigator, I am responsible for the conduct of this research study at my site. I am familiar with Good Clinical Practice (GCP) and will protect the rights and welfare of human subjects by adhering to applicable federal, state and local regulations governing clinical research. I further certify that:**

<input type="checkbox"/>	<p>My research staff and I have read the Belmont Report and understand the three underlying ethical principles:</p> <ul style="list-style-type: none"> <li>• respect for persons</li> <li>• beneficence</li> <li>• justice</li> </ul> <p>These principles will be upheld during the conduct of the research at this site.</p>
<input type="checkbox"/>	I will follow the protocol and will not implement any changes in the conduct of the research, such as protocol amendments, without prior written approval from the Copernicus Group IRB.
<input type="checkbox"/>	I have read the CGIRB Investigator Guidebook and agree to operate in compliance with CGIRB procedures set forth
<input type="checkbox"/>	<p>I agree that either I or someone under my supervision will verbally explain the subject information and consent form to all potential subjects and legally authorized representatives (LARs), if applicable, before obtaining their dated signature on the subject information and consent form and before performing any study-related procedures.</p> <p>Furthermore, I will allow adequate opportunity for potential subjects to read and review the subject information and consent form, ask questions and make their decisions regarding whether they will participate in the study. I will ensure the circumstances of the consent process minimize the possibility of coercion or undue influence. I will have an impartial witness present during the consent process when a subject or LAR is unable to read or is visually impaired.</p>
<input type="checkbox"/>	I agree that I will spend sufficient time to maintain appropriate oversight of the research protocol and research staff, including recruitment, selection of study participants and study conduct and to appropriately delegate research responsibilities. I also agree that I have adequate data and safety monitoring in place for ongoing research.
<input type="checkbox"/>	I agree that the privacy of the subjects and the confidentiality of the study data will be maintained at my site.
<input type="checkbox"/>	I will notify Copernicus Group IRB of all changes in research study activities, such as unanticipated problems involving risks to human subjects or others.
<input type="checkbox"/>	I will make myself available to discuss concerns and complaints regarding research subjects with the subject, subject representative, Sponsor/CRO and CGIRB during and after the conduct of this research protocol.
<input type="checkbox"/>	I am aware that the Copernicus Group IRB has the right to visit this study site at any time with appropriate notice.

**Signature of Principal Investigator (Required)**

**Signature Date (Required)**

**Printed Name of Principal Investigator (Required)**