



Investigator Site Questionnaire for Registry Studies

Internal Use

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 YES, please submit an Investigator Site Questionnaire for Additional Sites for each additional site – http://www.cgirb.com/tcg/forms.php)			

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

Day phone # (Mandatory): _____

24-hour phone # (Mandatory): _____

REGULATORY INFORMATION

- 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)
- 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
- 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)

SUBJECT INFORMATION AND CONSENT FORM

- 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: _____

*Note that certified translations must be approved by the IRB prior to use.

5. **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): _____

6. **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

7. **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

SUBJECT COMPENSATION FOR PARTICIPATION IN THE RESEARCH STUDY

(This information will be included in your site-specific subject information and consent form)

- 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.*

STUDY CONDUCT

8. **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 IRB approval prior to use

9. **If pediatric participants will be enrolled in this study, do you require written assent for minors age 7 and older?**

- No (Attach explanation) Yes N/A

10. **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): _____

Signature of Principal Investigator (Required)

Signature Date (Required)

Printed Name of Principal Investigator (Required)