

 	<h2>Investigator Site Questionnaire for Additional Sites</h2>	<p>Internal Use</p>
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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: _____	

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): _____

RESEARCH SITE AND COMMUNITY INFORMATION

- How would you generally describe your research setting? (Check only one box)
 Rural Suburban Urban Other (describe): _____
- Setting of the study site:
 Hospital Research Clinic Private Practice Other (describe): _____
- 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): _____
- Are you aware of any state or local laws that would impose stricter or additional requirements than those federally recognized for subject information and consent form? No Yes

If **YES**, provide details: _____

- 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.
- Has this facility been granted permission for this research to be conducted? _____
- What is the distance between the nearest hospital and the research site? _____

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

- Crash Cart Emergency Meds CPR certified staff and dial 911
 Other (describe): _____

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

- Interpreters Counseling services Bilingual staff members
 Other (Specify): _____ N/A

10. 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)

11. 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

12. 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? | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| b. Medical licensure in any state? | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| c. Other professional licensure/ registration? | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| d. Membership on any hospital staff? | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| e. Clinical privileges? | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| f. Professional society memberships or fellowship/board certifications? | <input type="checkbox"/> No | <input type="checkbox"/> Yes |

13. 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)

Signature of Principal Investigator (Required)

Signature Date (Required)

Printed Name of Principal Investigator (Required)