

 	<h2>Site-specific Change Request Form</h2>	<p>Internal Use</p>
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Please note that changes noted in Sections 1,2,6,8 and 9 require a change to your approved subject information and consent form. Acknowledgement of other changes is issued only at the site's request and by the agreement of the sponsor.

Blank & incomplete answers will result in delayed reviews!

Principal Investigator:	Protocol #:
IRB Tracking #:	

REQUESTED CHANGE(S) *Check all that apply and complete indicated sections. Complete signature block at end of form.*

This is a request for CGIRB to review the following modification(s) to activities at this investigator's site:
Please type or print clearly

- CHANGE OF SITE PHONE NUMBER **Complete Section 1**
- CHANGE OF 24 HOUR SITE CONTACT NUMBER **Complete Section 2**
- CHANGE OF SITE FAX NUMBER **Complete Section 3**
- CHANGE OF E-MAIL **Complete Section 4**
- CHANGE OF SITE CONTACT **Complete Section 5**
- RELOCATION OR CHANGE OF RESEARCH ADDRESS **Complete Section 6**
- CHANGE IN MAILING ADDRESS **Complete Section 7**
- ADDITION OF ANOTHER FACILITY WHERE RESEARCH WILL TAKE PLACE **Complete Section 8**
- CHANGE IN SITE SPECIFIC INFORMED CONSENT WORDING **Complete Section 9**
- ADDITION OR DELETION OF A SUBINVESTIGATOR **Complete Section 10**
- ADDITION OR DELETION OF A LAB / CHANGE OF LAB ADDRESS **Complete Section 11**
- OTHER CHANGE **Complete Section 12**

SECTION 1 Change of Site Phone Number

From:	To:
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SECTION 2 Change of 24 Hour Site Contact Phone Number

From:	To:
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SECTION 3 Change of Site Fax Number

From:	To:
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SECTION 4 Change of Site E-mail Address

From:	To:
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SECTION 5 Change of Site Contact

New Site Contact Name:	Phone and extension:	E-mail:
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SECTION 6 Relocation or Change of Research Address

Change Type: <input type="checkbox"/> Primary Address <input type="checkbox"/> Other Research Address	
From:	To:
<p><i>Answer the following questions regarding the site:</i></p> <p>6a. How would you generally describe this research setting? <input type="checkbox"/> Rural <input type="checkbox"/> Suburban <input type="checkbox"/> Urban <input type="checkbox"/> Other: _____</p> <p>6b. Setting of the study site: <input type="checkbox"/> Hospital <input type="checkbox"/> Research Clinic <input type="checkbox"/> Private Practice <input type="checkbox"/> Other: _____</p> <p>6c. Does a local IRB have jurisdiction over this site? <input type="checkbox"/> No <input type="checkbox"/> Yes If <u>YES</u>, submit a <i>Transfer of IRB Obligations Form</i> or equivalent documentation.</p> <p>6d. Distance between the nearest hospital and the research site: _____</p> <p>6e. Describe the on-site emergency equipment available for the subjects: <input type="checkbox"/> Crash Cart <input type="checkbox"/> Emergency Meds <input type="checkbox"/> CPR certified staff and dial 911 <input type="checkbox"/> Other (describe): _____</p> <p>6f. Describe additional resources unrelated to emergency care: <input type="checkbox"/> Interpreters <input type="checkbox"/> Counseling services <input type="checkbox"/> Other (List): <input type="checkbox"/> N/A</p>	

SECTION 7 Change of Mailing Address

From:	To:
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SECTION 8 Addition of Another Facility where Research Will Take Place

Study Site Name:		
Address:		
City:	State:	Zip:

Answer the following questions for newly added site:

- Day phone # (Mandatory):** _____ **24-hour phone # (Mandatory):** _____
- 8a. How would you generally describe this research setting?**
 Rural Suburban Urban Other:
- 8b. Setting of the study site:**
 Hospital Research Clinic Private Practice Other:
- 8c. What are the specific community attitudes towards the conduct of research in the local community that the IRB should be knowledgeable of prior to reviewing this study for this additional site?**
 Neutral Positive Negative (explain): _____
- 8d. Does a local IRB have jurisdiction over this site?**
 No Yes
 If **YES**, submit a **Transfer of IRB Obligations Form** or equivalent documentation.
- 8e. Distance between the nearest hospital and the research site:** _____
- 8f. Describe the on-site emergency equipment available for the subjects:**
 Crash Cart Emergency Meds CPR certified staff and dial 911
 Other (describe): _____
- 8g. Has FDA, OHRP, or any other regulatory agency inspected/evaluated the research site within the past 5 years?** No Yes
 If **YES**, was a Form FDA 483 or list of objectionable observations issued? No Yes
 If **YES**, attach 483 or list of objectionable observations and response letter
- 8h. Has the research site ever been issued any of the following? (select all that apply)**
 If **YES**, attach all documentation including responses
- NIDPOE (Notice of Initiation of Disqualification Proceedings and Opportunity to Explain)
 - Suspension
 - FDA Warning Letter
 - No, none of these has been issued
- 8i. Has any patient or subject ever made a complaint against this research site or the PI?**
 No Yes If **YES**, attach documentation including resolution steps

SECTION 9 Change in Site Specific Informed Consent

From:	To:
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SECTION 10 Addition or Deletion of a Sub-Investigator

From:	To:
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SECTION 11 Addition or Deletion of a Lab/Change of Lab Address

From:	To:
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SECTION 12 Other Change

From:	To:
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Signature of Principal Investigator (or Authorized Site Designee)	Signature Date
Printed Name of Principal Investigator (or Authorized Site Designee)	