

 	<p>Immediate Response Required</p> <p>Continuing Review Status Report</p>	<p>Internal Use</p>
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To ensure continuing review is conducted prior to study expiration, a completed *Continuing Review Status Report* must be received by the IRB prior to the assigned continuing review meeting date.

Blank & incomplete answers will result in delayed reviews!

Principal Investigator Name:
Protocol ID:
IRB Tracking Number:

SECTION ONE:

- This research study is: (please choose one)
- Active, **NO** subjects have been enrolled (Please Skip to Section Five)
 - Active, subjects have been enrolled
 - Enrollment is closed and site is still open (eg, Subject Follow-up)

SECTION TWO:

<p>List the information for the <i>most recently signed Subject Information and Consent Form (SICF)</i>:</p> <p>Approval Date: _____ Subject Signature Date: _____ Subject ID: _____</p>
<p>List the information for the <i>most recently signed HIPAA Authorization (if separate from the SICF)</i>:</p> <p><input type="checkbox"/> Not Applicable – combined with SICF or site is a non covered entity</p> <p>Approval Date: _____ Subject Signature Date: _____ Subject ID: _____</p>
<p>List the type, approval date, signature date, and subject ID for any additional informed consent forms (ie, sub-study consent, etc.). Add additional information as needed.</p> <p>Type: _____</p> <p>Approval Date: _____ Subject Signature Date: _____ Subject ID: _____</p> <p>Type: _____</p> <p>Approval Date: _____ Subject Signature Date: _____ Subject ID: _____</p>

SECTION THREE: Do Not Include Screen Failures

3A. Of the number enrolled/randomized how many remain in the study?	_____
3B. Of the number of enrolled/randomized how many completed the study?	_____
3C. Of the number of enrolled/randomized how many withdrew/discontinued from the study?	_____
<p>*Provide an explanation below for each subject's withdrawal/discontinuation (Attach a separate sheet if necessary) _____</p>	
TOTAL Number of subjects enrolled (3a+3b+3c) Do Not Include Screen Failures	_____

SECTION FOUR:

	YES	NO
<p>4A. Have any non-English speaking subjects been enrolled in this study?</p> <p style="text-align: right;"> <input type="checkbox"/> YES <input type="checkbox"/> NO </p> <p>If YES, provide the approval date of the CGIRB-approved certified translation of the subject information and consent form that was used for non-English speaking subjects.</p> <p style="text-align: right;">Approval Date: _____</p>		
<p>4B. Have there been any unanticipated problems involving risks to research subjects or others at your site that have not been reported to CGIRB?</p> <p>Examples:</p> <ul style="list-style-type: none"> • Safety report that is serious, unexpected, and related to participation • Significant protocol deviations that affect the rights and welfare of the subjects or the integrity of the study data <p>If YES, ensure these have been submitted to CGIRB for review</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>4C. Have any subject complaints about the research been received at your site that have not previously reported to CGIRB?</p> <p>If YES, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>4D. Have any unexpected benefits to participants been observed at your site that have not been reported to CGIRB?</p> <p>If YES, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>4E. Has any subject sought compensation for injury associated with this study at your site that has not been reported to CGIRB?</p> <p>If YES, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION FIVE:

	YES	NO
<p>5A. Has a regulatory inspection (eg, FDA, OHRP) occurred at the site since the start of the study or since your last continuing review?</p> <p style="text-align: right;"> <input type="checkbox"/> YES <input type="checkbox"/> NO </p> <p>If 5A is YES, was a Form FDA 483 or other list of objectionable observations issued?</p> <p style="text-align: right;"> <input type="checkbox"/> YES <input type="checkbox"/> NO </p> <p>If YES, attach the observations and your response letter.</p>		
<p>5B. Have you received a revocation, sanction or suspension of your state medical license since the start of the study or since your last continuing review?</p> <p>If YES, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5C. Any new findings or relevant information that may affect the risk/benefit ratio of this study?</p> <p>If YES, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5D. Have you modified the protocol without sponsor and IRB approval?</p> <p>If YES, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5E. Any change in principal investigator?</p> <p>If YES, who is the new principal investigator? _____</p> <p>For changes in PI, a final study status report <u>must</u> be completed and submitted to CGIRB by the currently approved PI. The submission packet for the new PI must be submitted at the same time. The new PI cannot be open until the previously approved PI has been closed.</p>	<input type="checkbox"/>	<input type="checkbox"/>

<p>5F. Any change at the site where research is conducted? If <u>YES</u>, ensure a change request form for each has been submitted to CGIRB for review</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5G. Any change in state or local laws or the community attitude with regard to clinical research? If <u>YES</u>, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5H. Any additional conflict of interest, financial or otherwise, for the principal investigator, sub-investigators, and research staff involved with the study OR each individual's respective family members? If <u>YES</u>, attach an explanation</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5I. Are you aware of any scientific publications or reports relevant to the risks and benefits of this research? If <u>YES</u>, attach a copy of each publication</p>	<input type="checkbox"/>	<input type="checkbox"/>

With my signature, I certify that the responses provided to all questions above are true and accurate. In addition, I certify that both my study staff and I have read the Belmont Report and understand the outlined ethical principles.

Signature of PI (Required)

Date of Signature (Required)

Printed Name of PI (Required)