

## Continuing Review Status Report

**Instructions:** Please read and complete all sections carefully and attach any necessary supporting documentation. Any missing information may result in a delay in the review.

<b>Sponsor:</b>	<b>Protocol #:</b>
<b>Principal Investigator's Name:</b>	
<b>Compass IRB #:</b>	

### Informed Consent Information

Please indicate which version of the Informed Consent you are currently using:	
Compass IRB Approval Date :	Compass IRB Version # :
In your professional opinion, is the Informed Consent still accurate and complete? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If "No," please explain:	

### Status Information

Please indicate which phase of the Study your site is currently in (check box that applies):	
<input type="checkbox"/> Open to Enrollment	
<input type="checkbox"/> Closed to Enrollment – Active Subjects	
<input type="checkbox"/> Closed to Enrollment – Subjects in Follow-Up	
<input type="checkbox"/> Study Completed – No further study-related activity at your site	

### Enrollment Information

Please fill in all number of subjects currently in each stage listed below:	
Total number of subjects that discontinued prematurely from the study who signed the ICF (screen failures, lost to follow up, withdrew consent, etc.)	+ ____
Number of active subjects:	+ ____
Number of subjects who have completed the study:	+ ____
Total number of subjects who have signed the ICF:	= ____
Please indicate the number of subjects that discontinued prematurely in each category:	
____ : Screen Fail	____ : Lost to Follow-Up
____ : Withdrew due to AE	____ : Other (please explain) -
List the number of subjects <b>consented</b> in each category:	
____ : Male	____ : Caucasian
____ : Female	____ : Middle Eastern
	____ : Native American
	____ : African Descent
	____ : Pacific Islander
	____ : Asian
	____ : Latino
	____ : Other

### Recruitment Information

Please check the box that applies:	
Are you currently recruiting for this study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has your site used any advertisements since your initial approval or your last report (whichever is most recent)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes," have these advertisements been approved by Compass IRB?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

### Study Events

Please check all applicable boxes that apply to any of the following events that may have occurred since your initial approval or your last report (whichever is most recent):			
Event	Yes	No	Submitted to and Approved by Compass?
Change of Site Location	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Change of Principal Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Change in Compensation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Audits by the FDA, Sponsor/CRO, or any IRB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any disciplinary action or change to P.I.'s license status (e.g. suspended or revoked) by the State Medical Board?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Change in financial or non-financial conflict of interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pregnancy of subject(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Complaint(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deaths	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Change to local or state laws concerning research on human subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Negative change to community attitude towards research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any other change to the risk/benefit analysis that has not yet been reported to Compass IRB?	<input type="checkbox"/>	<input type="checkbox"/>	--
If any "Yes" boxes have been checked and the item has not been submitted to Compass IRB, please submit that information with this report.			

### Verification of Initial Submission Information:

Has the contact person for this study changed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the P.I. or site staff received any human subject protection training since your initial approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No
How many ongoing studies are currently active and enrolling at your site?	_____
If any "Yes" boxes have been checked and the item has not been submitted to Compass IRB, please submit that information with this report.	

### Verification of Principal Investigator's Responsibility:

Have you personally conducted/supervised this study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has all research activity been conducted according to the approved study plan?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you reported Serious Adverse Events, Unanticipated Problems and Protocol Deviations as required by Compass IRB?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Has the Informed Consent been presented to all subjects in an appropriate manner?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you implemented appropriate additional measures for the protection of any subjects that may be considered to be a member of a vulnerable population?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**Document Summary**

To the best of your knowledge, have all changes to the approved research been submitted to and approved by the IRB?  Yes  No

**I hereby certify that I have fully disclosed all information pertaining to this event and that the above-referenced information is accurate.**

Submitting Signature (P.I. or Sub-Investigator only):	
_____	_____
Name	Title
_____	_____
Signature	Date

<b>COMPASS IRB INTERNAL USE ONLY:</b>		CIRB Staff ID: _____
Is this report appropriate for review?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If "No," please list reason that report is inappropriate for review:		
<b>Decision of Reviewer:</b>		
<input type="checkbox"/> Approved to Continue	<input type="checkbox"/> Request additional information*	
	<input type="checkbox"/> Call Site / Sponsor for discussion*	
	<input type="checkbox"/> Request Audit*	
	<input type="checkbox"/> Send to Full Board	
Comments/Notes (as needed):		
_____		_____
Signature of Board Reviewer		Date
* If checked, please attach all follow-up documentation to this report and resubmit to Board Reviewer.		

Please mail or fax this form to (480) 832-7376.