

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.

Sponsor:	Protocol #:
Principal Investigator's Name:	
Compass IRB #:	

Informed Consent Information

Please indicate which version of the primary Informed Consent you are currently using:	
Compass IRB Approval Date :	Compass IRB Version # :
If your study uses more than one consent at a time (e.g. Pharmacogenetic ICF, HIPAA), please list below the most current version of each that have been approved for your site:	
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"/> Site Not Yet Initiated by Sponsor <input type="checkbox"/> Open to Enrollment <input type="checkbox"/> Closed to Enrollment – Active Subjects and/or 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 and/or subjects in follow-up:	+ _____
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 (<i>please explain</i>) -
List the number of subjects consented 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? Yes No

Has your site used any advertisements since your initial approval or your last report (whichever is most recent)? Yes No

If “Yes,” have these advertisements been approved by Compass IRB? Yes No 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 *If yes and the death was not reported to CIRB, please explain why this death was not reported. <input type="checkbox"/> Death not Study Related <input type="checkbox"/> Other _____	<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? Yes No

Has the P.I. or site staff received any human subject protection training since your initial approval? Yes 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? Yes No

Has all research activity been conducted according to the approved study plan? Yes No N/A

Have you reported all appropriate Unanticipated Problems and Protocol Deviations as required by Compass IRB? Yes No N/A

Has the Informed Consent been presented to all subjects in an appropriate manner?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Have you implemented appropriate 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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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

COMPASS IRB INTERNAL USE ONLY:		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:		
Decision of Reviewer:		
<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, email to submissions@compassirb.com,
or fax this form to (480) 832-7376.**