

Close-Out Report

Instructions: Please read and complete all sections carefully. Any missing information may result in a delay in the review.

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

Informed Consent Information

Please indicate the most current version of the Informed Consent you have on file:	
Compass IRB Approval Date :	CIRB 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 verify your site's status by checking the following applicable boxes.	
<input type="checkbox"/> Enrollment has closed at my site.	
<input type="checkbox"/> All subjects at my site have completed all their study visits.	
<input type="checkbox"/> Any and all subject follow-up has been completed.	
<input type="checkbox"/> I have had my final monitoring visit and/or the Sponsor has closed-out my site for this study.	
<input type="checkbox"/> This study did not start at my site (e.g. Sponsor or Investigator decided not to initiate 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, withdrew consent, lost to follow-up, etc.)			+ ____
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 Consent	
____ : Withdrew due to AE	____ : Other		
List the number of subjects consented in each category:			
____ : Male	____ : Caucasian	____ : African Descent	____ : Asian
____ : Female	____ : Middle Eastern	____ : Pacific Islander	____ : Latino
	____ : Native American	____ : Other	

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.			

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
Have final run copies of all approved advertisements been submitted to Compass IRB?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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

I hereby certify that I have fully disclosed all information pertaining to my conduct of this study 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 Close-Out	<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.