

## HOW TO COMPLETE THE CONTINUING REVIEW STATUS REPORT

Please note that this report is an essential document for Board review for Investigator re-approvals. The CIRB staff will begin sending reminders approximately 30 days prior to your due date.

Please read and complete all sections carefully and attach any necessary supporting documentation. Any missing information may result in a delay in the review which could result in lapse of approval for the site. If you still have questions about this report, please contact us at (480) 832-7373.

### 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>	

**Your Compass IRB # is located at the top of every Notice of Approval issued to you for this project.**

#### 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 form, please indicate the version of the consent form that has been approved for use for your study (AA) _____	
<b>This is the approval date in the footer of your consent document.</b>	<b>This information can be found in the footer of your consent document.</b>
In your professional opinion, the information provided is still accurate and complete? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>	
If "No," please explain:	
<b>Please note this this is asking specifically about all of the most current versions that have been issued to your site.</b>	

#### 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:	= _____

Compass IRB Version Control	4
Doc. No.: CRS	Rev. _____
<b>This number should match the total of the previous three numbers.</b>	

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 ( <i>please explain</i> ) -		
List the number of subjects <b>consented</b> in each category:			
_____ : Male	_____ : Caucasian	_____ : African Descent	_____ : Asian
_____ : Female	_____ : Middle Eastern	_____ : Pacific Islander	_____ : Latino
	_____ : Native American	_____ : 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 *If yes and the death was <b>not</b> 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 provide that information with this report.			

**If you answer “Yes” to any of these questions in the Study Events section and the material in question has not yet been submitted to the IRB, you must do so 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.	

**This number should include the study you are completing the report for.**

**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 <input type="checkbox"/> N/A
Have you reported all appropriate Unanticipated Problems and Protocol Deviations as required by Compass IRB?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<b>If your site has not had any Unanticipated Problems or Protocol Deviations to report, your answer should be "N/A."</b>	
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

**Please note that the Board may have considered your study to involve a vulnerable population. If your site is a specialized center, please evaluate whether the additional steps that you may take as "standard practice" could be defined as "appropriate measures."**

**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

<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:	

**Decision of Reviewer:**

Approved to Continue

Request additional information\*

Call Site / Sponsor for discussion\*

Request Audit\*

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](mailto:submissions@compassirb.com),  
or fax this form to (480) 832-7376.**