

Sponsor Annual 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 #:
Compass IRB #:	

Protocol and Informed Consent Verification

Please indicate which version of the protocol your study sites should be currently using:	
Please indicate which version of the primary Informed Consent template your study sites should be 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 versions that are currently in use:	
Are you anticipating the need for an update to the Protocol and/or the Informed Consent template(s) in the next 30 days? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If "Yes," please explain the anticipated need for the forthcoming update:	

Status Information

Please indicate which phase of enrollment your study is currently in (check box that applies):	
<input type="checkbox"/> Study Not Yet Started or Currently on Hold <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 any of your study sites	
<p>Please indicate whether any of the following have occurred in or been published pertaining to your study since either the initial review or the last annual report (whichever is more recent). If you indicate "Yes" that any of these events or items have occurred, please provide a written summary of these events and how / to which extent they affected the conduct and integrity of the study.</p>	
<ul style="list-style-type: none"> • Unanticipated problems involving risks to subjects or others • Adverse Events • Subject withdrawals (and the reasons associated with the withdrawals) • Complaints about the research • Amendments or modifications (including, but not limited to, the protocol and / or Investigator's Brochure) • Any relevant multi-center trial reports, data monitoring committee (DMC) or data safety monitoring board (DSMB) reports, published or unpublished current risk-potential benefit assessment based on study results, or recent relevant literature. 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No

Recruitment Information

Please check the box that applies:	
Are you currently recruiting for this study?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
What is the number of subjects that have been enrolled thus far?	_____

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 research and that the above-referenced information is accurate.

Submitting Signature (Sponsor / CRO designee):	
_____	_____
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"/> 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.		