

HOW TO COMPLETE THE SPONSOR ANNUAL REVIEW STATUS REPORT

Please note that this report is an essential document for Board review when being considered for annual re-approval. The CIRB staff will begin sending reminders approximately 30 days prior to your due date. These questions pertain to your study as a whole, not just those sites under the review of Compass IRB.

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 study.

Sponsor:	Protocol #:
Compass IRB #:	

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

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 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 _____ that are currently in use:
<div style="background-color: #f0f0f0; padding: 5px; display: inline-block;"> This information can be found in the footer of your consent document(s). </div>
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
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.
<ul style="list-style-type: none"> • Unanticipated problems involving risks to subjects or others <input type="checkbox"/> Yes <input type="checkbox"/> No • Adverse Events <input type="checkbox"/> Yes <input type="checkbox"/> No • Subject withdrawals (and the reasons associated with the withdrawals) <input type="checkbox"/> Yes <input type="checkbox"/> No • Complaints about the research <input type="checkbox"/> Yes <input type="checkbox"/> No • Amendments or modifications (including, but not limited to, the protocol and / or Investigator's Brochure) <input type="checkbox"/> Yes <input type="checkbox"/> No • 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

If you answer "Yes" to any of these occurrences, please note that we do not need to necessarily receive the individual reports, but rather would like a written summary of what this new information is, if it has been evaluated by the Study Team and what it means to the study as a whole.



GUIDING YOU TO SUCCESS

5416 East Baseline Road, Suite 120
Mesa, AZ 85206
(877) 660-1IRB
Direct: (480) 832-7373
Fax: (480) 832-7376
www.compassirb.com

Recruitment Information

Please check the box that applies:

Are you currently recruiting for this study? Yes No N/A

What is the number of subjects that have been enrolled thus far? _____

This is asking for the total number that have signed the consent/enrolled. It is not intended to represent the total dosed, randomized or started any study procedures.

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 N/A

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? Yes No

If "No," please list reason that report is inappropriate for review:

Decision of Reviewer:

Approved to Continue

Request additional information*

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.