

## Research Status Report Form [Multicenter – Sponsor/CRO] Page 1 of 6

*To be completed by the Sponsor/CRO or their designee at the time designated by Aspire IRB for continuing review of the protocol (normally one year after initial review, but may be sooner).*

Sponsor: _____	Protocol #: _____	Expiration Date: _____
Protocol Title: _____		
<b>SECTION 1: REPORT TYPE</b>		
<input type="checkbox"/> Study Continuation – Subjects are still being seen <input type="checkbox"/> Final / Study Completed – Study is complete, all subjects at all sites have completed all protocol mandated study visits and follow-up <input type="checkbox"/> Closed to Enrollment – Subjects are still in follow-up or data collection is continuing <input type="checkbox"/> Study has not begun – <i>complete Question 1.a.</i> 1.a. <input type="checkbox"/> First subject not enrolled yet <input type="checkbox"/> Study cancelled or terminated <input type="checkbox"/> Study is on hold <input type="checkbox"/> Other: _____		
<b>SECTION 2: PROTOCOL AMENDMENTS</b>		
Have there been any amendments / modifications to the protocol since the previous continuing review? <input type="checkbox"/> Yes – <i>complete Appendix A and attach a summary of all amendments / modifications.</i> <input type="checkbox"/> No		
<b>SECTION 3: SITE INFORMATION</b>		
<i>Please enter responses for each item below by providing information for all sites participating in the above referenced study / protocol. Provide information relative to the study sites approved by Aspire IRB only.</i>		
a. Number of sites <u>actively participating</u> in the study:	_____	
b. Number of sites that have <u>completed</u> the study:	_____	+
c. Number of sites that have <u>withdrawn / discontinued</u> their participation in the study: <i>[Complete Appendix B.]</i>	_____	+
d. <b>TOTAL NUMBER OF SITES THAT HAVE PARTICIPATED IN THIS STUDY:</b>	_____	=
e. Number of sites being overseen by another IRB:	_____	
f. Do you anticipate adding additional sites to the study? <input type="checkbox"/> No <input type="checkbox"/> Yes – if yes, how many? _____		
g. Have any sites reported any significant protocol deviations/violations to the Sponsor? <input type="checkbox"/> No <input type="checkbox"/> Yes – <i>please attach a summary.</i>		
h. Is the integrity of the study in jeopardy because of significant protocol deviations/violations? <input type="checkbox"/> No <input type="checkbox"/> Yes – <i>please explain why the study should continue.</i>		
<b>SECTION 4: SITE MONITORING</b>		
<i>Please enter responses for each item below by providing information for all sites participating in the above referenced study / protocol. Provide specific information/explanations relative only to the study sites approved by Aspire IRB.</i>		
a. How have sites been monitored for this study?		
b. Have any deficiencies been found that might represent an increased risk to study subjects? <input type="checkbox"/> No <input type="checkbox"/> Yes – <i>please explain.</i>		

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**SECTION 4: SITE MONITORING (continued)**

- c. Has Aspire IRB been notified of these additional identified risks?  
 No – *please explain.*  Yes
- d. Have any general informational or alert letters been sent to the sites about frequently occurring GCP deficiencies identified through the monitoring process?  
 No  Yes – *please attach copies of this /these item(s).*

**SECTION 5: SUBJECT INFORMATION**

*Please enter responses for each item below by providing information for all sites participating in the above referenced study / protocol. Provide information relative to the study sites approved by Aspire IRB.*

- a. What is the subject enrollment goal for the study/protocol? \_\_\_\_\_
- b. What is the anticipated date of last subject enrolled? \_\_\_\_\_
- c. What is the anticipated date of last subject completed? \_\_\_\_\_
- d. How many subjects are still actively participating or being followed in the study? \_\_\_\_\_
- e. How many subjects have completed the study? \_\_\_\_\_
- f. How many subjects have withdrawn or been discontinued from the study?  
*Please attach a summary of the reasons for subject withdrawals / discontinuations.* \_\_\_\_\_
- g. Have there been any complaints about the research?  No  Yes – *please attach a summary.*

**SECTION 6: SAFETY MONITORING INFORMATION**

*Please enter responses for each item below by providing information for all sites participating in the above referenced study / protocol. Provide information relative to the study sites approved by Aspire IRB.*

- a. Please attach a summary (since the last IRB review) of:
- Adverse events, untoward events, and adverse outcomes experienced by subjects.
  - Unanticipated problems involving risks to subjects or others.
  - Complaints about the research.
- b. Has the Sponsor acquired any information that materially changes the potential benefits of the study as described in the original protocol and consent form?  
 No  Yes – *please explain (attach separate sheet).*
- c. Is there a DSMB for this study?  
 No – *go to c.*  
 Yes When was the last meeting of the DSMB?  
 Have copies of DSMB reports been provided to Aspire IRB?  
 No - *please provide copies at this time.*  Yes
- d. Have IND Safety Reports have been submitted to the FDA for the study drug?  
 Yes – *please provide a listing of all IND Safety Reports submitted to FDA, including dates.*  No  N/A
- e. Has the Sponsor noted any trends or patterns in relation to AEs, IND Safety Reports or DSMB findings to date that suggest any increased risks to subjects in the study?  
 No – *go to f.*  
 Yes Has this information been provided to study sites?  
 No  Yes – *please attach copies of the information provided to the sites that has not been previously provided to Aspire IRB.*

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**SECTION 6: SAFETY MONITORING INFORMATION (continued)**

- f. Has the Sponsor conducted timely information searches (including literature searches) regarding the test article?  
 No – *go to g.*  
 Yes Has this information been provided to study sites?  
 No – *please explain why not.*  
 Yes Have the results of the information search suggested an increased risk to subjects enrolled in this study?  
 No  Yes – *please provide a summary.*
- g. Has any new information regarding study risks been communicated to study subjects in any form other than the Informed Consent Document?  
 No  Yes – *attach copies of communication(s) provided to the subjects.*
- h. Has there been a change to the Sponsor's assessment of the risk/benefit ratio based on study results?  
 No  Yes – *please explain.*

**SECTION 7: RESEARCH STATUS REPORT FORM CHECKLIST**

The following information must be completed in Appendix C with your Research Status Report Form by the submission deadline in order to be guaranteed placement on the agenda:

- Date of Current Protocol  
 Date of Current Investigator's Brochure (IND Studies) OR  
 Date of Package Insert if revision has occurred after study approval date. (FDA approved drugs only)  
 Date(s) of Current Multicenter Informed Consent Document(s)

Additional information that you feel may be useful to the Board in considering continuing approval for this protocol

- N/A  Included – *describe below.*

As a representative of the Sponsor/CRO of this study, I certify that the information contained above is correct to the best of my knowledge, as of \_\_\_\_\_ (insert date).

Sponsor/CRO Representative Name: \_\_\_\_\_  
 Title/Company: \_\_\_\_\_  
 Phone Number: \_\_\_\_\_  
 Fax Number: \_\_\_\_\_  
 Email: \_\_\_\_\_

Signature of Sponsor/CRO Representative

Date





