



**Research Status Report Form  
(Sponsor/CRO – Multicenter/Registry Study)  
Page 2 of 6**

**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- f. How many subjects have withdrawn or been discontinued from the study?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 d.*  
 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.*

**Research Status Report Form  
(Sponsor/CRO – Multicenter/Registry Study)  
Page 3 of 6**

**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 \_\_\_\_\_

**Research Status Report Form  
(Sponsor/CRO – Multicenter/Registry Study)  
Page 4 of 6**

**APPENDIX A  
Protocol Amendments & Addenda**

NONE

Amendment/Addendum Number	Date	Consent Changes Made?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
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		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
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