

Site Status Report Form

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Please complete ALL sections and respond to ALL questions.

OMISSION OF ANY INFORMATION MAY DELAY REVIEW OF YOUR SUBMISSION & RESULT IN NON-COMPLIANCE.

1. Sponsor: _____	2. Protocol #: _____	3. Due Date: _____
4. Protocol Title: _____		
5. Principal Investigator: _____		
6. Site Address: _____		
7. Report Type: <ul style="list-style-type: none"> <input type="checkbox"/> Study Continuation – Subjects are still being seen <input type="checkbox"/> Final/Study Completed – Study is completed; no subjects currently enrolled <input type="checkbox"/> Closed to Enrollment – Subjects are still in follow-up or data collection is continuous <input type="checkbox"/> Study has not begun – <i>complete Question 7.a.</i> <ul style="list-style-type: none"> 7.a. <input type="checkbox"/> First subject not enrolled yet <input type="checkbox"/> Study is on hold <input type="checkbox"/> Study Cancelled or Terminated <input type="checkbox"/> Principal Investigator withdrew <input type="checkbox"/> Other: _____ 		
8. Study Documents – Provide the Board with the dates of the following documents currently being used by the site for this study.		
a. Protocol Version Date: _____		
b. Investigator Brochure Version Date: _____ <input type="checkbox"/> N/A		
c. IRB-approved Informed Consent Document Version Date: _____		
d. IRB-approved Child Assent Document Version Date: _____ <input type="checkbox"/> N/A		
e. IRB-approved Minor Consent Document Version Date: _____ <input type="checkbox"/> N/A		
f. Other IRB-approved Consent Addenda Version Date: _____ <input type="checkbox"/> N/A		
9. Audit / Monitoring Information		
a. Has your site been audited/inspected since the approval of this study (Sponsor, FDA, etc.)?		
<input type="checkbox"/> Yes – provide copies of audit reports or a summary of findings. <input type="checkbox"/> No		
b. Is there any new information that would affect the scientific validity of the study?		
<input type="checkbox"/> Yes – provide an explanation. <input type="checkbox"/> No		
10. Census Information – Please be sure to enter a number for a, b, c, d and e and that a+b+c+d = e.		
a. Number of subjects still actively participating or being followed in the study: _____		
b. Number of subjects who have completed the study: + _____		
c. Number of subjects who have withdrawn or were discontinued from the study: + _____		
<i>Attach a listing of withdrawn / discontinued subjects (Subject # only) and reasons for withdrawals / discontinuations.</i>		
d. Number of subjects who were screen failures (consented but never randomized): + _____		
e. TOTAL NUMBER OF SUBJECTS WHO HAVE BEEN CONSENTED FOR THIS STUDY: = _____		
f. Subjects consented by gender: Male: _____ Female: _____		

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11. Vulnerable Subject Populations	
<p>a. Did you enroll any subjects from a vulnerable population?</p> <p><input type="checkbox"/> Yes – <i>check all that apply.</i> <input type="checkbox"/> No – <i>go to Question 12.</i></p> <p><input type="checkbox"/> Children / minors (anyone under the age of majority in your state) <i>Note: 18 yr. olds are considered minors in Alabama and Nebraska.</i></p> <p><input type="checkbox"/> Economically and/or educationally disadvantaged <input type="checkbox"/> Limited or non-readers / illiterate individuals</p> <p><input type="checkbox"/> Nursing home residents / institutionalized individuals <input type="checkbox"/> Prisoners <input type="checkbox"/> Decisionally impaired individuals</p> <p><input type="checkbox"/> Employees / immediate family <input type="checkbox"/> Students <input type="checkbox"/> Hearing / visually impaired individuals</p> <p><input type="checkbox"/> Non-English speaking individuals – <i>complete b, c & d.</i> <input type="checkbox"/> Other (specify): _____</p>	
<p>b. Was an explanation of specific measures used to safeguard these subjects during the recruitment and consent processes previously submitted to the Board?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No – <i>provide an explanation of specific measures at this time.</i></p>	
<p>c. What was/were the native language(s) of the Non-English speaking subjects enrolled? <input type="checkbox"/> N/A</p> <p><input type="checkbox"/> Spanish <input type="checkbox"/> Chinese <input type="checkbox"/> French <input type="checkbox"/> German <input type="checkbox"/> Other (specify): _____</p>	
<p>d. Were non-English speaking subjects provided IRB-approved consent forms in their native language(s)? <input type="checkbox"/> N/A</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No – <i>provide an explanation of the consent process that was used.</i></p>	
12. Study Information – Have any of the following events occurred that have <i>NOT</i> been previously reported to the IRB?	
<p>a. Serious adverse events or any adverse events considered to be unexpected and related? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>b. Significant protocol deviations / violations? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>c. Unanticipated problems involving risks to subjects or others? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>d. Data Safety Monitoring Board reports, relevant multi-center trial reports, or other interim findings? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>e. Changes in subject compensation? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>f. Subject complaints? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>g. New information that may affect the subjects' willingness to continue participation? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>h. Have any subjects sought compensation for injury? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>i. Are you aware of any recent literature relevant to the study? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>j. Change to the Principal Investigator's risk/benefit ratio assessment based on study results? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>k. Please attach a summary <u>since your last IRB review of:</u></p> <ul style="list-style-type: none"> • Adverse events, untoward events, or outcomes experience by subjects. • Unanticipated problems involving risks to subjects or others. • Complaints about the research. • Amendments and modifications. 	
13. Investigator Status – Have any of the following events occurred that have <i>NOT</i> been previously reported to the IRB?	
<p>a. Change in Principal Investigator? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>b. Change in Sub-Investigator(s)? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>c. Change in licensure, board certification or hospital privileges of Principal or Sub-Investigator(s)? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>d. Criminal or medical complaints resulting in investigation of Principal or Sub-Investigator(s)? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p> <p>e. Change in conflicts of interest for the Investigator, Sub-investigator(s) or staff? <input type="checkbox"/> Yes * <input type="checkbox"/> No</p>	



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14. Investigator Training	
Has the Principal Investigator completed research-related training and/or education in the areas of Good Clinical Practice and Protection of Human Subjects within the past two years?	<input type="checkbox"/> Yes <input type="checkbox"/> No*
I acknowledge, as Principal Investigator, that the information provided in response to the above questions is true and accurate.	
<i>Signature of Principal Investigator</i>	<i>Date</i>

*** ATTACH AN EXPLANATION**