

## 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:		
<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>		
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: _____		
<b>8. Study Documents</b> – 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		
<b>9. Audit / Monitoring Information</b>		
a. Has your site been audited/inspected since the approval of this study (Sponsor, FDA, etc.)? <input type="checkbox"/> Yes – <i>provide copies of audit reports or a summary of findings.</i> <input type="checkbox"/> No		
b. Is there any new information that would affect the scientific validity of the study? <input type="checkbox"/> Yes – <i>provide an explanation.</i> <input type="checkbox"/> No		
<b>10. Census Information</b> – 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 <b>still actively participating or being followed</b> in the study: _____		
b. Number of subjects who have <b>completed</b> the study:      +      _____		
c. Number of subjects who have <b>withdrawn or were discontinued</b> 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Attach a listing of withdrawn / discontinued subjects (Subject # only) and reasons for withdrawals / discontinuations.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 <b>screen failures</b> (consented but never randomized):      +      _____		
e. <b>TOTAL NUMBER OF SUBJECTS WHO HAVE BEEN CONSENTED FOR THIS STUDY:</b> =      _____		
f. Subjects consented by gender:      Male: _____      Female: _____		

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### 11. Vulnerable Subject Populations

- a. Did you enroll any subjects from a vulnerable population?
- Yes – *check all that apply.*     No – *go to Question 12.*
- Children / minors (anyone under the age of majority in your state)  
*Note: 18 yr. olds are considered minors in Alabama and Nebraska.*
- Economically and/or educationally disadvantaged       Limited or non-readers / illiterate individuals
- Nursing home residents / institutionalized individuals     Prisoners     Decisionally impaired individuals
- Employees / immediate family       Students     Hearing / visually impaired individuals
- Non-English speaking individuals – *complete b, c & d.*     Other (specify): \_\_\_\_\_
- b. Was an explanation of specific measures used to safeguard these subjects during the recruitment and consent processes previously submitted to the Board?
- Yes     No – *provide an explanation of specific measures at this time.*
- c. What was/were the native language(s) of the Non-English speaking subjects enrolled?       N/A
- Spanish     Chinese     French     German     Other (specify): \_\_\_\_\_
- d. Were non-English speaking subjects provided IRB-approved consent forms in their native language(s)?       N/A
- Yes     No – *provide an explanation of the consent process that was used.*

### 12. Study Information – Have any of the following events occurred that have **NOT** been previously reported to the IRB?

- a. Serious adverse events or any adverse events considered to be unexpected and related?       Yes \*     No
- b. Significant protocol deviations / violations?       Yes \*     No
- c. Unanticipated problems involving risks to subjects or others?       Yes \*     No
- d. Data Safety Monitoring Board reports, relevant multi-center trial reports, or other interim findings?       Yes \*     No
- e. Changes in subject compensation?       Yes \*     No
- f. Subject complaints?       Yes \*     No
- g. New information that may affect the subjects' willingness to continue participation?       Yes \*     No
- h. Have any subjects sought compensation for injury?       Yes \*     No
- i. Are you aware of any recent literature relevant to the study?       Yes \*     No
- j. Change to the Principal Investigator's risk/benefit ratio assessment based on study results?       Yes \*     No
- k. Please attach a summary since your last IRB review of:
- 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 **NOT** been previously reported to the IRB?

- a. Change in Principal Investigator?       Yes \*     No
- b. Change in Sub-Investigator(s)?       Yes \*     No
- c. Change in licensure, board certification or hospital privileges of Principal or Sub-Investigator(s)?       Yes \*     No
- d. Criminal or medical complaints resulting in investigation of Principal or Sub-Investigator(s)?       Yes \*     No
- e. Change in conflicts of interest for the Investigator, Sub-investigator(s) or staff?       Yes \*     No



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<b>14. Investigator Training</b>	
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? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No*</span>	
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**