



Research Status Report Form

Page 1 of 2

Please complete ALL sections and respond to ALL questions.

OMISSION OF ANY INFORMATION MAY DELAY APPROVAL OF YOUR SUBMISSION & RESULT IN A LAPSE OF IRB APPROVAL

1. Sponsor: _____	2. Protocol #: _____	3. Expiration 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 – complete Question 7.a.		
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 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		
<i>Please be sure to enter a number for a, b, c, d and e and that a+b+c+d = e.</i>		
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c. Number of subjects who have withdrawn or were discontinued from the study: _____ + _____		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Attach a listing of withdrawn / discontinued subjects (Subject# only) and reasons for withdrawals / discontinuations.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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Page 2 of 2

11. Vulnerable Subject Populations

- a. Did you enroll any subjects from a vulnerable population?
 Yes – *check all that apply* No – *go to Question 12*
 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
 Nursing Home Residents / Institutionalized Persons Prisoners Decisionally impaired
 Employees / Immediate family Students Hearing / visually impaired
 Non-English speaking - *complete 11.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 - *please 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 the Non-English speaking subjects provided with IRB approved written consent forms in their native language? N/A
 Yes No – *provide an explanation of the consent process that was used*

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

- a. Serious Adverse Events? Yes * No
- b. Significant Protocol Deviations / Violations? Yes * No
- c. Unanticipated problems? Yes * No
- d. Data Safety Monitoring Board reports? 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

13. Investigator Status – Have any of the following events occurred, which 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, Subinvestigator(s) or staff? Yes * No
- f. Principal Investigator has completed research related training and/or education in the area of Good Clinical Practices and Protection of Human Subjects within the past two years? Yes No*

I acknowledge, as Principal Investigator, that the information provided in response to the questions of the IRB is true and accurate.

Signature of Principal Investigator

Date

*** ATTACH AN EXPLANATION**