



## Research Status Report Form

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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 or Sponsor'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.

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<b>13. Investigator Status</b> – <i>Have any of the following events occurred that have <b>NOT</b> been previously reported to the IRB?</i>	
a. Change in Principal Investigator?	<input type="checkbox"/> Yes * <input type="checkbox"/> No
b. Change in Sub-investigator(s)?	<input type="checkbox"/> Yes * <input type="checkbox"/> No
c. Change in licensure, board certification or hospital privileges of Principal or Sub-investigator(s)?	<input type="checkbox"/> Yes * <input type="checkbox"/> No
d. Criminal or medical complaints resulting in investigation of Principal or Sub-investigator(s)?	<input type="checkbox"/> Yes * <input type="checkbox"/> No
e. Change in conflicts of interest for the Investigator, Sub-investigator(s) or staff?	<input type="checkbox"/> Yes * <input type="checkbox"/> No
<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?	
	<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**