



### SCIENTIFIC REVIEW FORM

Protocol #:

Principal Investigator:

Title:

**Principal Investigator:**

Date of Review:  Due Date for all Reviews:

Biostatistician (if applicable):

**Scientific Reviewer**

ITEMS	ASSESSMENT	COMMENTS
<b>Scientific Review</b>		
Are the specific aims and corresponding hypotheses clearly stated?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Is the primary outcome (and secondary outcomes as appropriate) stated and defined?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Has an appropriate literature search been performed such that that the rationale for the study has been adequately presented? (When risks to the subject are high, an extensive search is essential.)	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Is the question or hypothesis being tested providing important knowledge to the field?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Are there adequate preliminary data in the literature (or from the investigator) to justify the research?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Is it feasible or reasonable to achieve the results in the proposed timeframe, including the ability to recruit, retain, or follow subjects?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Are the proposed tests or measurements appropriate to answer the scientific question?	<input type="checkbox"/> YES <input type="checkbox"/> NO	



Are all the proposed tests or measurements requested necessary to answer the scientific question?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Are the individuals who are conducting the trial properly qualified and trained to perform the procedures included in the protocol?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Does the research present risk to the subjects and if so, is it acceptable?	<input type="checkbox"/> YES <input type="checkbox"/> Acceptable <input type="checkbox"/> Unacceptable <input type="checkbox"/> NO	
How do the risks of the new treatment/therapy compare to standard treatment/therapies?	<input type="checkbox"/> Greater <input type="checkbox"/> About the same <input type="checkbox"/> Lower	
Is any standard of care denied as part of this study? (If yes, specify)	<input type="checkbox"/> YES <input type="checkbox"/> NO	
If the protocol includes a placebo that might entail a risk (even if not great), is the placebo essential for the conduct of the trial? (Have/Should other study designs been/be considered?)	<input type="checkbox"/> YES <input type="checkbox"/> NO	

ITEMS	ASSESSMENT	COMMENTS
<b>Gender, Minorities and Children</b>		
Are there appropriate inclusion of gender, minorities and children?	<input type="checkbox"/> YES <input type="checkbox"/> NO	

**Reviewer's overall assessment**

Please check one of the following:

- This protocol is acceptable in its present format.
- This protocol is acceptable, pending clarifications from the Principal Investigator (list below)
- This protocol is NOT acceptable for the reasons stated below

**Reviewer's overall score**

Please check one of the following:

- 1.0 – 1.5 Outstanding
- 1.6 – 2.0 Excellent
- 2.1 – 2.5 Very Good
- 2.6 – 3.0 Good
- 3.1 – 3.5 Acceptable
- Unscored Unacceptable



**Reviewer's other comments/questions**

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