

DIVISION OF IMMUNOLOGY

SCIENTIFIC REVIEWER FORM

Please note:

- **Protocols submitted to the CTSU do not require additional Division review**
- **Three-year rewrites of BCH protocols do not require review providing they were reviewed initially by the Division**

Scientific Reviewer:

Date of Review:

Principal Investigator:

Protocol Title:

Protocol #:

RETURN COMMENTS <u>DIRECTLY TO THE PI</u> BY: If no follow-up action is required by the PI, you may return the form to Jeanne Testa.
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ITEMS	ASSESSMENT	COMMENTS
Scientific Review		
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? <i>*When risks to the subject are high, an extensive search is essential.</i>	<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	

Items	Assessment	COMMENTS
Scientific Review		
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? ↳ If YES, is it acceptable?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> YES <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 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 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 <input type="checkbox"/> YES <input type="checkbox"/> NO	
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
- Un-scored Unacceptable

Reviewer's other comments/questions

- Follow-up action or response is required
- The following is a recommendation only (no follow-up required)

Reviewer's other comments/questions—Continued

Reviewer Signature

Principal Investigator's Responses & Correspondence

Designated Scientific Approval Signature

Date