



Scientific Review Checklist

(This checklist is appropriate for studies that include both biomedical and social/behavioral research)

Section 1: Institution and Study Information	
Full Study Title:	
Principal Investigator:	Study ID:
Primary IRB:	FDA-Regulated?: (Drug Device Other)
Reviewer Name:	Review Date:
Email:	

Section 2: Background and Objectives	
Are the research title and question clearly and accurately stated?	
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present
Reviewer's Comments:	
Are the objectives clearly stated to address the research question and hypothesis?	
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present
Reviewer's Comments:	
Is the current standard of care/state of the art described?	
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present
Reviewer's Comments:	
Have the investigators presented enough information to follow the logic behind the development of the project and where the project fits in the current standard of care/state of the art?	
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present
Reviewer's Comments:	
Is the review of the literature current (past 3-5 years), critical and balanced?	
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present
Reviewer's Comments:	
Are gaps in the literature articulated in a manner that further supports the execution of the protocol?	
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present
Reviewer's Comments:	

Section 3: Design			
Does the proposed design address the question?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
Will the proposed design enable the investigators to meet the objectives?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
If applicable, are the controls appropriate?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			
Do inclusion and/or exclusion criteria take into account confounding variables?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
Are the inclusion and/or exclusion criteria so strict as to prevent generalizability of results or hinder a reasonable rate of recruitment?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
Does the proposal address possible need to stop the study due to either unanticipated problems, or because the findings suggest the approach is far superior to the current standard of care that it would be unethical to withhold it from the general population?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
Section 4: Methods			
Is there enough information presented, within reason, for you to reproduce the study?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
Is information provided on key equipment used in the study, e.g., make and model, brief description of how the equipment is used within the standard of care, how it is used for the research under review (not a reference to an investigational device that is the subject of the study)?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			
If applicable, do investigators have permission to use survey instruments?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			
If applicable, are appropriate references provided for survey instruments?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			
When appropriate, is blinding adequate? Is a plan in place to regularly monitor the consistency of the blinding practices?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			
If deception is involved, has the plan for informing the subjects of the true intent of the study and the deceptive means employed been addressed?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			

Section 5: Data Collection			
Are the requested data elements the “minimum necessary” to conduct the study?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Are the correct data elements being collected to meet the primary and secondary endpoints?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Is there a functional data collection sheet that permits both ease of data collection and ease of data analysis?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Is there a plan to maintain the master list with identifying information?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
If social security numbers are being collected, then is there adequate justification presented for their use, and is the use in compliance with DoDI 1000.30, Reduction of Social Security Number (SSN) Use Within DoD?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Are there data elements that might be useful to the project that the investigators are NOT collecting?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Is there a data security/data management plan in place?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Section 6: Feasibility			
Do the investigators’ and/or their collaborators’ CVs indicate that they have the expertise to execute the methods?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Is the necessary equipment available or can it reasonably be purchased or leased (not a reference to an investigational device that is the subject of the study)?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Is information provided that would suggest enrollment goals can be met?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			
Does the investigator have the necessary clinical coordinator support?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer’s Comments:			
If this is a greater than minimal risk study, then has a Research Monitor been identified, and is that person appropriately qualified for that role?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer’s Comments:			
Is the proposed schedule for the study realistic?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer’s Comments:			

Section 7: Endpoints		
Are endpoints provided?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		
Do the endpoints align with the objectives?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		

Section 8: Statistical Analysis		
Is the statistical analysis plan outlined in the protocol?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		
Are the endpoints used in the statistical analysis?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		
When appropriate, is a sample size calculation provided?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		
Has subject attrition been considered?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		
Have concepts such as missing data, intention to treat analysis and stratification been addressed?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		
Has the team met with a statistician or do they have their own statistical support?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		

Section 9: Pre-IRB Review Considerations			
If you read the consent document, then are there issues that should be addressed now?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			
Is there consistency throughout the protocol, e.g., number of subjects, timing and number of visits?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	
Reviewer's Comments:			
Is benefit demonstrated appropriately in greater than minimal risk research?			
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present	<input type="checkbox"/> Not Applicable
Reviewer's Comments:			

Section 10: Overall Assessment	
Please identify your overall assessment of this study:	
<input type="checkbox"/> Forward to IRB for Consideration	
<input type="checkbox"/> Forward to IRB with Comments	
<input type="checkbox"/> Return to Investigator with Comments	
Reviewer's Signature:	Date: