



Research Regulatory Oversight Office

IP-006
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INFORMATION PAPER

Scientific Review of Human Research Studies

Information Papers published by the OUSD(P&R), R2O2 contain background information on specific issues raised to this Office, policies covering the issues and the OUSD(P&R), R2O2 interpretation of those policies. These papers may include policy interpretations that are enforceable within and among all institutions in the OUSD(P&R).

Background

Since it is unethical to conduct research involving human subjects if the studies are not scientifically sound, Department of Defense (DoD) institutions engaged in non-exempt human subjects research shall have procedures in place to ensure the scientific rigor and validity of proposed studies under review by an institutional review board (IRB). To ensure this, the DoD requires that DoD IRBs conducting ethical reviews for compliance with DoD Instruction (DoDI) 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*, consider the findings of a scientific review when making their regulatory determinations. The DoDI 3216.02 has extended this requirement to non-exempt DoD-supported research conducted by non-DoD institutions as well.

Policy

Enclosure 3, Section 3.a.(2) of DoDI 3216.02 states “The DoD institution shall have policies and procedures to require scientific review of non-exempt research involving human subjects and to ensure this review is considered during the IRB review process.” Section 4.b.(2) of Enclosure 3 addresses the need for non-DoD IRBs to consider the “scientific merit” of a study by stating, “When a non-DoD institution is conducting non-exempt research involving human subjects, the IRB review must consider the scientific merit of the research, as required by section 219.111 of” Title 32 Code of Federal Regulation (CFR) (the “Common Rule”).

Policy Interpretation and Implementation Requirements for OUSD(P&R) Institutions

In accordance with the DoDI 3216.02, all IRBs within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) are required to consider the scientific review recommendations during their determination deliberations and are further required to document that the scientific review recommendations were considered. The scientific review report must be included with all other protocol documents as part of the package for ethical review. Additionally, when reviewing studies that have been approved by a non-DoD IRB, DoD personnel conducting reviews must also examine submissions for evidence that the scientific merit of the studies under their review were considered by the primary IRB, and document such in their reviews.

OUSD(P&R) institutions shall establish local policies and procedures for ensuring compliance with the DoDI 3216.02 requirements regarding scientific review. Those local policies are subject to R2O2 review and approval. The procedures followed are also subject to review by R2O2 during assistance visits and audits; however, approval of local business processes and procedures are not subject to R2O2 approval prior to implementation. R2O2 has modified existing templates for scientific review of non-exempt research involving human subjects. Those templates are included in this Information Paper beginning at page 3, and are available electronically upon request.

Documentation of scientific review and its consideration during ethical reviews shall accompany each non-exempt study. Documentation of the scientific review can be accomplished using a template such as one of those included in this Information Paper or a locally generated checklist. Documentation of the consideration of that scientific review during the ethical review may include a notation in IRB minutes and/or notation on a review checklist for non-exempt HRPO or other review. Furthermore, if a research activity is an internal information collection as defined in DoDI 8910.01, *Information Collection and Reporting*, then the Report Control Symbol (RCS) or Office of Management and Budget (OMB) review will satisfy the scientific review requirement.

Summary of requirements:

1. Scientific review report must be included with all other protocol documents reviewed by DoD IRBs.
2. DoD IRBs must consider the scientific review recommendations during the ethical review process.
3. DoD IRBs must document their consideration of scientific review recommendations as part of the ethical review process.
4. DoD reviewers conducting ethical reviews of non-exempt studies reviewed by non-DoD IRBs must document in their reviews that the scientific merit of the studies was considered by the non-DoD IRB in accordance with 32 CFR 219.111.

Definitions

HRPO:	an individual who is delegated the responsibilities as defined in paragraph (a)(2) of section 252.235-7004 of title 48, Code of Federal Regulations. There may be more than one HRPO in a DoD Component. Some DoD Components may use a different title for the person(s) with the defined responsibilities.
Human Subject:	a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information. (32 CFR 219.102(f)).
DoD Internal Information Collection:	a collection of information from two or more OSD or DoD Components that require approval by the DoD Internal Information Collections Officer, who resides in WHS. ¹
DoD Public Information Collection:	a collection of information whereby information is collected by the DoD from the public. The PICO processes all DoD public information collections for OMB approval.
Research:	a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (32 CFR 219.102(d)).

¹ Examples of these would be if a survey draws subjects from two or more Military Services or if a survey draws subjects from a Military Service and another OSD or DoD Component from a sample of 10 or more persons as individuals or representatives of agencies that elicit attitudes, opinions, behaviors, and related demographic, social, and economic data to identical questions that are to be used for statistical compilations for research and/or policy assessment purposes.





Research Regulatory Oversight Office

Scientific Review Checklist – Biomedical Research

(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:	Email:	Review Date:

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 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 research question?		
<input type="checkbox"/> Present/Acceptable	<input type="checkbox"/> Present/Not Acceptable	<input type="checkbox"/> Not Present
Reviewer's Comments:		

<p>Will the proposed design enable the investigators to meet the objectives?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>If applicable, are the controls appropriate?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>Do inclusion and/or exclusion criteria take into account confounding variables?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Are the inclusion and/or exclusion criteria so strict as to prevent generalizability of results or hinder a reasonable rate of recruitment?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>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?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>

Section 4: Methods

<p>Is there enough information presented, within reason, for you to reproduce the study?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Is information provided on key equipment used in the study, <i>e.g.</i>, 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)?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>If applicable, do investigators have permission to use survey instruments?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>If applicable, are appropriate references provided for survey instruments?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>



When appropriate, is blinding adequate? Is a plan in place to regularly monitor the consistency of the blinding practices?

Present/Acceptable Present/Not Acceptable Not Present 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?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Section 5: Data Collection

Are the requested data elements the "minimum necessary" to conduct the study?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Are the correct data elements being collected to meet the primary and secondary endpoints?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Is there a functional data collection sheet that permits both ease of data collection and ease of data analysis?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Is there a plan to maintain the master list with identifying information?

Present/Acceptable Present/Not Acceptable 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*?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Are there data elements that might be useful to the project that the investigators are NOT collecting?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Is there a data security/data management plan in place?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:



Section 6: Feasibility
<p>Do the investigators' and/or their collaborators' CVs indicate that they have the expertise to execute the methods?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present </p> <p>Reviewer's Comments:</p>
<p>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)?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present </p> <p>Reviewer's Comments:</p>
<p>Is information provided that would suggest enrollment goals can be met?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present </p> <p>Reviewer's Comments:</p>
<p>Does the investigator have the necessary clinical coordinator support?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable </p> <p>Reviewer's Comments:</p>
<p>If this is a greater than minimal risk study, then has a Research Monitor been identified, and is that person appropriately qualified, and have the time and resources to perform in this role?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable </p> <p>Reviewer's Comments:</p>
<p>Is the proposed schedule for the study realistic?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present </p> <p>Reviewer's Comments:</p>

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

Section 8: Statistical Analysis
<p>Is the statistical analysis plan outlined in the protocol?</p> <p> <input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present </p> <p>Reviewer's Comments:</p>



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

Section 9: Pre-IRB Review Considerations

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

Section 10: Overall Assessment

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





Research Regulatory Oversight Office

Scientific Review Checklist – Social and Behavioral Science Research

Section 1: Institution and Study Information	
Full Study Title:	Principal Investigator:
Primary IRB:	Study ID:
Reviewer Name: Email:	Review Date:

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 recognized/accepted practice 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 recognized/accepted practice?	
<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 research 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:	

<p>If applicable, are the controls appropriate?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>Do inclusion and/or exclusion criteria take into account confounding variables?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Are the inclusion and/or exclusion criteria so strict as to prevent generalizability of results or hinder a reasonable rate of recruitment?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>

Section 4: Methods

<p>Is there enough information presented, within reason, for you to reproduce the study?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>If applicable, do investigators have permission to use survey instruments?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>If applicable, are appropriate references provided for survey instruments?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>When appropriate, is blinding adequate? Is a plan in place to regularly monitor the consistency of the blinding practices?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present <input type="checkbox"/> Not Applicable</p> <p>Reviewer's Comments:</p>
<p>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?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>

Section 5: Data Collection

<p>Are the requested data elements the "minimum necessary" to conduct the study?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
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<p>Are the correct data elements being collected to meet the primary and secondary endpoints?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Is there a functional data collection sheet that permits both ease of data collection and ease of data analysis?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Is there a plan to maintain the master list with identifying information?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>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, <i>Reduction of Social Security Number (SSN) Use Within DoD</i>?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Are there data elements that might be useful to the project that the investigators are NOT collecting?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>
<p>Is there a data security/data management plan in place?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>

Section 6: Feasibility		
<p>Do the investigators' and/or their collaborators' CVs indicate that they have the expertise to execute the methods?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>		
<p>Is the necessary equipment available or can it reasonably be purchased or leased (not a reference to equipment that is the subject of the study, but instead, support equipment such as computers, telephones, copiers, etc.)?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>		
<p>Is information provided that would suggest enrollment goals can be met?</p> <p><input type="checkbox"/> Present/Acceptable <input type="checkbox"/> Present/Not Acceptable <input type="checkbox"/> Not Present</p> <p>Reviewer's Comments:</p>		



Is the proposed schedule for the study realistic?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Section 7: Endpoints

Are endpoints provided?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Do the endpoints align with the objectives?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Section 8: Statistical Analysis

Is the statistical analysis plan outlined in the protocol?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Are the endpoints used in the statistical analysis?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

When appropriate, is a sample size calculation provided?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Has subject attrition been considered?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Have concepts such as missing data, intention to treat analysis, and stratification been addressed?

Present/Acceptable Present/Not Acceptable Not Present

Reviewer's Comments:

Has the team met with a statistician or do they have their own statistical support?

Present/Acceptable Present/Not Acceptable 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?

- Present/Acceptable
 Present/Not Acceptable
 Not Present
 Not Applicable

Reviewer's Comments:

Is there consistency throughout the protocol, *e.g.*, number of subjects, timing and number of visits?

- Present/Acceptable
 Present/Not Acceptable
 Not Present

Reviewer's Comments:

Is benefit demonstrated appropriately in greater than minimal risk research?

- Present/Acceptable
 Present/Not Acceptable
 Not Present
 Not Applicable

Reviewer's Comments:

Section 10: Overall Assessment

Please identify your overall assessment of this study:

- Forward to IRB for Consideration
 Forward to IRB with Comments
 Return to Investigator with Comments

Reviewer's Signature:

Date:



The Uniformed Services of the United States