NAVAL POSTGRADUATE SCHOOL

Institutional Review Board
Scientific Review Form

This form is required for all non-exempt research protocols.

Purpose: Navy policy requires an independent review of research for scientific merit or scholarship prior to IRB review. A completed scientific review form is required in all applications for IRB review and approval of new non-exempt research.

Form Instructions:
Please submit this Scientific Review Form to your Department Chair, Director, Dean (if in GSDM), or other individual designated as an IRB Scientific Reviewer in your organization along with your IRB application package. Scientific reviewers will review the IRB application and research proposal when determining the scientific merit of the research. Reviewers can require investigators to revise their submissions if they find that the submission inadequately addresses the points below. Scientific reviewers may not conduct a scientific review for their own studies. Scientific reviewers must meet the CITI Ethics training requirements for Scientific Reviewers.

MAC users please use Adobe Reader for Macintosh. Do not use Apple Preview. Free Adobe reader can be found here.
For questions regarding this form or process send an e-mail to IRB@nps.edu.

A. Protocol Basics

Study Title	
Principal Investigator	
Co-Investigator(s)	
Student Researcher(s)	
PI's Email	
PI's Department	
Date	

B. Scientific Review Criteria

Please indicate whether the following criteria have been met by choosing YES if the statement is true or NO if the statement is false. Please choose N/A if the statement does not apply to this study.	**YES**	**NO**	**N/A**
Research Team			
1. To the best of your knowledge, does the membership of the research team provide adequate expertise to perform all aspects of the proposed study? *See IRB application Part 1, Q2.*	☐	☐	

Scientific Merit	YES	NO	N/A
2. Does the proposal have a valid research hypothesis and/or appropriate objectives? Has a literature review been completed? *See IRB application Part 1, Q6.*	☐	☐	
3. Does the protocol provide sufficient information to justify the conduct of the study?	☐	☐	
4. Is the study design adequate to achieve study objectives? *See IRB application Part 1, Q7.*	☐	☐	
5. Is there a method to investigate the research question(s) that would not require the use of human subjects?	☐	☐	
6. Is the target subject group appropriate for this study? *See IRB application Part 1, Q13-15.*	☐	☐	
7. Has the PI demonstrated careful consideration of subject inclusion and exclusion criteria? *See IRB application Part 1, Q14.*	☐	☐	
8. Has the PI provided an adequate rationale for the stated sample size? *Consider the proposed participant population, sample size, and estimated study duration. See IRB application Part 1, Q15.*	☐	☐	
9. Is it likely that the PI will be able to meet his/her enrollment goals?	☐	☐	☐
10. If the study warrants a data safety monitoring plan is it appropriate? *See IRB application Part 1, Q26.*	☐	☐	☐
Research Risks and Benefits	**YES**	**NO**	**N/A**
11. Is the risk/benefit ratio favorable? *See IRB application Part 1, Q19-Q22.*	☐	☐	
12. Have all potential risks been accurately and fully described in the application and consent form (unless waived)? *See IRB application Part 1, Q19-Q22.*	☐	☐	
13. Have risks to subjects been minimized by employing sound scientific design? *See IRB application Part 1, Q20 & Consent Form.*	☐	☐	
14. In your opinion should the IRB review the research sooner than annually or monitor the process?	☐	☐	
15. Could risk to subjects be further reduced in any way? If yes, please explain.	☐	☐	
16. Should this study be submitted to the safety office? If yes, please explain.	☐	☐	

C. Conflict of Interest

Do you have a conflict of interest with the proposed research?

☐ YES ☐ NO

If yes, provide details:

D. Reviewer Recommendations

Based on the information provided by the investigator:

☐ **This research can be submitted to the IRB as currently written.**

☐ **This project does not possess scientific merit.**

☐ **This project requires the revisions described below and must be re-reviewed by the scientific reviewer prior to submission to the IRB.**

Scientific Reviewer Name:

☐ **I am up to date with my CITI Scientific Reviewer training**

Scientific Reviewer Signature:

Date: