



Purpose: To request review of a proposed activity to determine if it involves human subject research. This form should be completed and submitted when an investigator proposes a project involving the observation or collection of information from or about people that s/he does not believe constitutes human subject research. Common activities that could result in the collection of information about people include but are not limited to:

- Administer a questionnaire or survey or conduct focus groups or interviews.
- Observe human performance directly or indirectly.
- Audio or video record the activities of humans.
- Use pre-collected (secondary) data that contains any information about humans (e.g. social media data, after action reports, data sets, etc.).
- Test any equipment in which humans will serve as users.

If you know your study will involve human subjects research, please skip the determination request process and submit an IRB application package.

Form Instructions: The investigator(s) must provide adequate information for the IRB Chair to determine whether the project constitutes human subject research.

To receive an official determination, submit the following to IRB@nps.edu.

1. Determination request form signed by the Principal Investigator (PI). *The PI for student research is the advisor.*
2. A copy of the research proposal or statement of work.
3. **Attach any data collection tools (i.e., interview or survey questions, etc.).**
4. Submit signed determination form and corresponding documents to IRB@nps.edu. An IRB administrator will contact you if additional information is needed.

For questions regarding this form or process send an e-mail to IRB@nps.edu.

A. Research Basics

Title of the Project	
Principal Investigator	
Co-Investigator(s)	
Student Researcher(s)	
PI's Email	
PI's Department	
Date	



B. Data Collection

	YES	NO
<p>1. Will the activity include the use of secondary information or biospecimens?</p> <p>Secondary information or biospecimens are forms of data that already exist or will be collected for another primary purpose such as fitness reports, personnel records, training records, after action reports, social media data, information from data repositories, existing survey data, biospecimens from salivary, tissue, or blood repositories, etc.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>If Yes, state the following below:</p> <p>a. Describe the type of information or biospecimens (training records, fitness reports, information on all active duty by specialty, biospecimens from a previous clinical trial, etc.).</p> <div style="background-color: #e0ffff; height: 150px;"></div>		
<p>b. List the secondary information variables or types of biospecimens to which you will have access. Make sure to include any PII or demographics contained in the information or biospecimen samples.</p> <div style="background-color: #e0ffff; height: 150px;"></div>		



	YES	NO
2. Will the activity involve interaction with people?	<input type="checkbox"/>	<input type="checkbox"/>

If Yes, describe what tasks subjects will be asked to perform (take a survey, be interviewed, participate in a simulation, play a game etc.) and what information subjects will be asked to provide.

Submit a copy of all data collection tools (ex: interview questions, questionnaires, etc.).

3. *Submit a copy of your project proposal.* If a proposal or statement of work is not available, describe the purpose of the data collection and how the data will be used.



	YES	NO
<p>4. Does the activity involve investigating a USMC topic or include USMC personnel? If yes, USMC IRB administrative review is required before beginning.</p> <p>If the NPS IRB provides you with a "not human subjects research" determination, you are required to email a copy of the determination to the USMC IRB Chair, Ms. Kerry Foshier, kerry.foshier@usmcu.edu. If your study receives a human subjects research" determination, you will submit your completed human subjects research protocol to Ms. Foshier after it has been approved by the NPS IRB.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5. Is this research part of a sponsored project (e.g., reimbursable, RIP, NRP)?</p> <p>If Yes, Please list JON if known: </p>	<input type="checkbox"/>	<input type="checkbox"/>

Principal Investigator Signature:

Date: