**Naval Postgraduate School**

**Institutional Review Board**

**Protocol Application**

**Instructions:** This form must be reviewed and completed in its entirety. A complete description of the planned research needs to be submitted to determine if all regulatory policy requirements have been met.

**This form is to be used for**

* **Initial IRB Applications (Part 1),**
* [**Amendments (Parts 1 and 2)**](#Amendment)**, and**
* [**Continuing Reviews (Parts 1 and 3)**](#ContinuingReview)

**OVERVIEW AND PROTOCOL CHECKLISTS**

Each section describes the steps that need to be completed for Initial IRB Applications, Amendments, and Continuing Reviews, and the documents that need to be submitted for each.

For further guidance or assistance, please contact the HRPP office at (831) 656-2043 or by email at IRB@nps.edu.

1. **Initial IRB Application** (for new research)

**PART 1: INITIAL IRB APPLICATION**

Instructions: For an Initial IRB Application, complete each section of the protocol and include all information requested. Delete all *italicized* guidance before submitting to the IRB for review. For an Amendment or a Continuing Review, ***use track changes*** to modify only those items that have changed.

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| **A. Protocol Basics**  |

**Date:**

**1. Research Title:**

**2. Investigators**. The Principal Investigator (PI) is the researcher who is ultimately responsible for the conduct of the research. For student research the PI is the thesis advisor. Investigators who are unaffiliated with NPS (including contractors) are not covered by the NPS assurance to conduct research with human subjects and may be required to obtain assurance.

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| **Principal Investigator****(The PI for student research is the advisor)** |  |
| Name | Title or Rank | Department or Org Name | InvestigatorRoles and Responsibilities |  |
|       |       |       |       |  |
| **Co-Investigators and Student Investigators** |  |
| Name | Title or Rank | Department, Org Name, and Service | InvestigatorRoles and Responsibilities | Federal EmployeeYes or No |
|       |       |       |       |  |
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**3.** **Estimated completion date of the research:**

If student research, list student graduation month/year.

**4. Is this research part of a sponsored project (e.g., reimbursable, RIP, NRP)?**

[ ]  No

[ ]  Yes. List the job order number (JON):

**5. Are you requesting an Exempt IRB review?**

If requesting an exempt review, the Scientific Review Form is not required:

If determined "not exempt" by the IRB, the Scientific Review Form will be required.

[ ]  No. **Skip to question 6**.

[ ]  Yes. To qualify as “exempt” **ALL** research activities proposed must fall into one of the following categories. Check all that apply. If all research activities do not fall into one or more of the categories described below check “No” to this question and proceed to Q6.

|  |  |
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| [ ]  | Research conducted in established or commonly accepted educational settings, involving normal educational practices. (E1) *This category may include research on effectiveness as well as comparisons about educational strategies, techniques, curricula or classroom management. Educational tests, such as cognitive, diagnostic, aptitude, achievement tests.*Notes: * The research must not adversely impact students’ opportunity to learn required educational content.
* The research must not adversely impact the assessment of educators who provide instruction.
* An information sheet or abbreviated consent document should be used
 |
| [ ]  | Research that ONLY includes surveys, interviews, focus groups, or observation of public behavior with adults who can consent for themselves and cover benign topics. (E2) (I-LR)(FR) Notes: * The term “benign” describes activities that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive.
* Interventions are not allowed.
* An information sheet or abbreviated consent document should be used.
 |
| [ ]  | Benign research on perception, cognition, motivation, communication, social behavior, behavioral games or minimal risk performance tasks. (E3)(LR)(FR) Notes: * The term “benign” describes activities that are brief in duration, not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive, and not likely to have a lasting adverse impact.
* An information sheet or abbreviated consent document may be used.
 |
| [ ]  | Secondary research use of identifiable private information or identifiable biospecimens originally collected for other purposes. (E4) Notes:* When the identifiable private information or biospecimens are publicly available;
* The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact the subjects or try to re-identify subjects.
 |

*General Notes:*

The above research may involve randomization between groups if disclosed to participants.

The above research may be audio recorded, if the subject agrees, if identities are not shared, and the confidentiality of the information is properly protected.

Exempt category 5 is not listed as it applies to projects conducted or supported by or subject to the approval of Federal department and agency heads. Please contact the HRPP office if you feel your project meets this criterion.

NPS will not implement exemption categories 7 & 8 at this time.

**6. Will research activities include collection, storage, and/or analysis of saliva or other biospecimens.**

[ ]  No

[ ]  Yes. If yes, complete and submit Appendix A: Biospecimen Collection (found on IRB website).

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| **B**. **Research Summary**  |

**7. Summarize the objective(s) of the research including purpose, research question, hypothesis & background information, literature, etc.**

     *Provide a summary. Do not state “see attached proposal.”*

**8. Describe the research study design**, **method, and proposed statistical analysis.**

     *Summarize the research design. Do not state “see attached proposal.”*

**9. Where will the research be performed?**

Remember to list the initial (base) location for the research project and to include any additional research sites. When considering the method of interaction keep in mind how likely someone will be to participate depending on what will be asked of them. Also, consider your request for audio recording. Which platform(s) are feasible and secure.

*State if conducted over the phone, through email, or online. If in person, list the name of the command(s), university/school(s), training site(s), ship(s) name, etc.*

Research activities involving in-person interactions:

[ ]  Acknowledge adherence to COVID-19 risk mitigation guidelines and compliance with local and federal ordinances throughout the current public health emergency.

**10. Will any research activities take place OCONUS**? A host country ethics review is required for all research conducted outside the US. Research conducted with non-US citizens, conducted in non-US territory may require a local ethics review.

[ ]  No

[ ]  Yes. Provide the locations:

**11. Does the research involve the use of existing records (i.e., secondary information or biospecimens)?**

Examples of 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.

[ ]  No

[ ]  Yes. Describe the records below. Include the variables and number of records to which you will have access.

*Include the following:*

* *Description of the records.*
* *List or attach on a separate page listing the variables provided in the records.*
* *State where the records are located.*
* *State the number of records you will access. Please state the number of unique individuals that will be represented in the record(s)*
* *Include a statement confirming an amendment will be submitted to the IRB if more records are received or needed.*

**12. Are the secondary information or biospecimens private (not available to the general public)?**

[ ]  No

[ ]  Yes, attached evidence of approval from the organization that owns the secondary information or biospecimens stating you may access them for your research.

**13. For what purpose will this secondary information or biospecimens be used?**

[ ]  To collect data that will be analyzed in the research.

[ ]  To identify potential subjects.

[ ]  Other. Describe below.

**14. The following areas of research require approval outside of NPS.** Check all that apply.

[ ]  Classified research

[ ]  Severe or unusual intrusions, either physical or physiological

[ ]  Potential or inherently controversial topics (those likely to attract media coverage or challenged by interest groups)

[ ]  Research involving Marine Corps population (requires USMC IRB administrative review and possibly USMC Survey Manager review and/or a General Officer approval letter)

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| **C.** **Subject Population**  |

**Proposed Study Populations**

If the proposed project includes:

1. More than one command and/or crossing commands
2. Crossing services (Navy, Army, USMC, etc.)
3. General public

Information Collection Approval(s) may apply. These can delay approval of your IRB protocol and targeted start date. For more information, see [Microsoft Word - IRB survey guidance - 2020-05-25 (nps.edu)](https://www.nps.edu/documents/103449465/105822173/IRB_Guidance_on_Survey_Approvals_and_Survey_Tips.pdf/e0cc19aa-5a79-443d-8a65-b00feef672ed?t=1590594492538). For additional guidance contact the HRPP office IRB@nps.edu.

**15. Subject Populations.** Check all that apply.

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | Military Personnel (outside NPS) | [ ]  | Government Contractors |
| [ ]  | DoD Personnel (outside NPS) | [ ]  | General Public |
| [ ]  | NPS Students | [ ]  | Pregnant Women or Fetuses |
| [ ]  | NPS Civilian Employees | [ ]  | Children, *under 18 years old* |
| [ ]  | Foreign Nationals outside the U.S. | [ ]  | Elderly, *over 70 years old* |
| [ ]  | Non-English Speakers | [ ]  | Prisoners |

Does this research include work on OPSEC sensitive subjects as determined by the NPS [Critical](https://cle.nps.edu/access/content/group/3e124ba3-c17c-4d23-a55b-ac81f085e843/Critical%20Information%20List/FY20%20NPS%20CIL-1.pdf) Information List (follow link below)?

[ ]  No

[ ]  Yes. Describe the countermeasures implemented to protect this information in accordance with [NPSINST 3070.1](https://nps.edu/documents/109948171/110107065/NPSINST-3070.pdf/8890ed27-3da1-85f4-2424-983f38b581fc?t=1597099611748)

**16. Describe subject inclusion and exclusion criteria.**

      *Specify the characteristics that must be met for individuals to be included and excluded from your study. Include the following:*

* *Any experiences such as positions held, deployments, training, that will qualify or disqualify subjects.*
* *Include age range, gender, service, and any other demographics that qualify or disqualify subjects.*
* *Please note minors (under the age of 18) require the assent from the minor and consent from the parents.*

**17. Provide the sample size (ex: 75) or range (ex: 75-100) and the rationale for why that number is chosen (e.g., based on a power analysis).**

      *Provide an accurate number or specific range. Once you have enrolled the approved number of subjects, enrollment must stop. A subject is considered enrolled when he or she has signed a consent form (or, in the case of an online survey, clicked agreement with the consent statement.) To increase enrollment after approval, the PI must submit an amendment for IRB review and approval. Note that recruitment and enrollment are different. You may recruit more individuals than you enroll. If your research only involves the analysis of secondary information or biospecimens, place a "0" in the box.*

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| **D. Recruitment & Consent Process**   |

**18. Describe how potential subjects will be recruited to participate in the research.**

      *Describe in detail the recruitment procedures (how you will ask potential subjects to participate in your research). Include the following:*

* *Describe how subjects are recruited (i.e., email, phone, in person, flyers, group presentations, etc.).*
* *State when and where potential subjects will be recruited.*
* *State the number of times each potential subject will be solicited to participate. For example, you may send out one solicitation then in two weeks send one follow-up.*
* *State the location where recruitment will take place.*
* *State who will conduct the recruitment.*
* *Include how potential subject contact information will be obtained.*

*Note: Senior leadership cannot participate or be present during recruitment activities.*

**19. How will you minimize coercion and undue influence during the recruitment process?**

      *Coercion occurs when an overt or implicit threat of harm is intentionally presented to obtain compliance. Undue influence occurs through an offer of an excessive or inappropriate reward or other overture to obtain compliance. Consider the following:*

* *Will officers and enlisted be recruited separately?*
* *Will an ombudsperson be used?*
* *Are instructors recruiting their own students?*
* *Are members of senior leadership suggesting, requesting, or claiming support of the research?*

**20. Describe how you will obtain consent from subjects and how the potential for coercion or undue influence will be minimized.** Note: if requesting a consent waiver please state that here and remember to review Section H.

      *Consent is a process. Describe how participants will be fully informed of this research prior to their participation and how their voluntary consent will be documented.*

*Include the following:*

* *Who is responsible for obtaining consent?*
* *When will subjects be provided with the consent form?*
* *Will they have time to review, consider, and ask questions about the research?*
* *Where will the consent process take place?*
* *When will consent be obtained?*
* *How is consent obtained (i.e., in person, over the phone, email, fax, etc.)?*

**Is the research regulated by the FDA?**

[ ]  No

[ ]  Yes. Consent may not be waived (32 CFR 219.116).

**21. Will you quote subjects?** Please note: when quoting, signed informed consent is required.

[ ]  No

[ ]  Yes

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| **E. Detailed Study Procedures**  |

**22.** **Describe in detail the tasks subjects will be asked to perform and the amount of time it will take to complete each task.**

**This section will most likely be the lengthiest.** *What will you ask your participants to do? When and where will they do it? How long will it take them to do it? Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect.*

*Identify the measurement/instrumentation.**For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project.* Address each item below as applicable.

*Include the following:*

* *Describe tasks in chronological order (i.e. consent, equipment calibration, data collection, post research activities, etc.).*
* *Provide enough detail so that someone not involved with the research would be able to read the description and understand exactly what you are asking subjects to do.*
* *State when and where each task will be completed.*
* *State how long each task is expected to take. This includes the time it takes to obtain consent, screening activities, calibration activities, data collection, and post research activities.*

*If your research only involves the analysis of secondary information or biospecimens, describe how the research team will obtain or have access to the records/specimens and how these data will be transmitted securely.*

**Will you audio or video record subjects?**

[ ]  No

[ ]  Yes. Describe what will be recorded, why you are recording, and how you will safeguard the recording.

      *Describe in detail what will be recorded, why you need to record and if the recording will be transcribed.*

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| **Description of the Technology that will be Used to Recruit Participants, Capture, Record, or Transmit Data*****Check all that apply and answer the questions in the relevant required section.*** |
| **Technology Type** | **Examples** |  | **If Yes, Answer the Required Questions** |
| Social Media | *For example, Facebook or Twitter* | YES [ ]  NO [ ]  | Provide Link(s):      Purpose:       |
| Website survey or similar tool | *For example, Qualtrics, surveys on external websites* | YES [ ]  NO [ ]  | Name of website survey, or similar tool you are using:      |
| Wearable Technology | *AR, VR, and eyetracking headsets Examples of wearable biosensors include accelerometers, activity trackers, wireless heart rate monitors, pulse oximetry sensors, and glucose sensors.* | YES [ ]  NO [ ]  | Name of the device(s):      |
| Phone, Video or Web ConferencingAudio Recording | *Examples include Zoom, Adobe Connect, Skype for Business, Facetime, etc., Microsoft Teams*During interviews and/or focus groups | YES [ ]  NO [ ]  | Name of the conferencing system:      Will recordings be captured?     Will digital recorders be used?YES [ ]  NO [ ]  |
| Cloud based storage | *Cloud storage is a cloud computing model in which data is stored on remote servers accessed from the internet, or “cloud.”* | YES [ ]  NO [ ]  | Identify:      Is this external from the authorized NPS cloud storage?YES [ ]  NO [ ]  |
| Other |  |  | Identify:       |

**23. Will compensation be given to research subjects?** Compensation may be monetary, raffles, meals/snacks, extra credit, etc.

[ ]  No

[ ]  Yes. Describe what the compensation consists of and the purpose for offering it.

      *Provide the following information:*

* *Explain why compensation is offered.*
* *State what the compensation consists of and the estimated dollar value.*
* *Describe how the level of compensation is determined.*
* *State the source of funding.*

*Compensation for DoD personnel during normal business hours must meet the requirements of DoDI 3216.02. Consult DoDI 3216.02 for policies on compensating research subjects.*

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| **F.** **Risks and Benefits**  |

**24. Does the research involve any of these possible risks or discomforts to subjects?** Check all that apply.

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| --- | --- | --- | --- | --- | --- |
| [ ]  | Use of deception | [ ]  | Social or economic risk | [ ]  | Presentation of materials that might be considered sensitive, offensive, threatening or degrading |
| [ ]  | Physiological risk | [ ]  | Manipulation of physiological or social variables such as sensory deprivation, social isolation, psychological stresses |
| [ ]  | Employment risk |
| [ ]  | Legal risk | [ ]  | Probing for personal or sensitive info or possible invasions of privacy of subjects or family’s |
| [ ]  | Physical risk |
| [ ]  | Psychological risk |

**25. Describe any foreseeable risks or discomforts associated with the research*.***

      *Common risks associated with research at NPS include: breach of confidentiality, breach of privacy, employment risk, stress reactions, and motion sickness. Describe each risk in detail including risks noted in Q23.*

**26. Explain what steps will be taken to minimize risks and discomforts (mentioned in Q23-24) and to protect subjects' welfare.**

      *Include a plan to minimize all risks mentioned in Q23-24.*

**27. Describe the potential benefits of this research for individuals, subjects, society, military, or DoD/DoN. Explain how risks are reasonable in relation to anticipated benefits.**

      *Explain how risks are reasonable in relation to anticipated benefits. The IRB will not approve research that does not provide potential benefits.*

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| **G.** **Data Security & Monitoring**  |

**28. Will you access, obtain, and/or record identifiers such as name, social security number, DoD ID #, address, telephone number or any combination of demographic data that could lead to the identification of a participant?**

[ ]  No

[ ]  Yes. Explain below why it is necessary to collect these identifiers, state if you will use a coding system to protect against disclosure of identifiers and state when PII will be destroyed.

      *Identifiers are more than just names and SSN. With enough demographic data, identification is possible (i.e., gender, ethnicity, marital status, rank, service, MOS, billets, assignment dates, etc.). If you are collecting POC information from subjects to recruit, schedule participation, or quote, you have PII and should include this in Q27.*

**29. How will data and consent forms be kept confidential during collection, analysis, and long-term storage after completion of the research?** Please note electronic PII may **only** be stored on the NPS network.

      *Please include the following information****:***

* *State who will have access to the data.*
* *State where the data will be kept (hard copy and electronic copy) during collection, analysis, storage, and at the completion of the research. Please note that personally identifiable information may not be stored on external hard drives (including flash/thumb drives) and may not be stored on a personal laptop computer.*
* *State who will maintain the data after the research is complete. (At completion all data must be de-identified and stored by the PI. It may be stored in the PI's locked office or on the NPS secure server. No data may be destroyed.) DON requires all data, research notes, and consent forms be kept for 30 years before forwarding to a federal record center.*
* *Recordings: How will they be stored and safeguarded. Please note that recordings cannot be deleted unless transcribed.*

**30. When appropriate, due to an elevated risk level, a research plan is required to make adequate provisions for monitoring the data to ensure the safety of subjects. Will you monitor data collection?**

[ ]  No

[ ]  Yes. Describe the monitoring procedure below.

      *Data monitoring allows the investigator to determine mid-research if:*

* *there is a need to change the research design or information presented to subjects,*
* *there are any unforeseen risks to subjects, or*
* *there is a change in the risks-benefit ratio. If it is appropriate for your research data to be monitored, describe your plan to monitor the data*.

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| **H. Consent Waivers.** **-** Not required for exempt studies.  |

**Waiver to Obtain/Document/Alter Informed Consent**

If your study *does not* qualify for exemption and you are requesting IRB approval to waive, alter, or not document informed consent, complete the applicable sections below. For exempt research, a waiver is not required; do not complete this section.

Whenever possible, potential research subjects should be given an explanation of what their voluntary participation entails as it relates to the risks, benefits, alternatives, study activities, and confidentiality of the IRB approved study. The potential subject’s agreement to participate is typically documented (e.g., signed by subject) on an IRB approved consent form. However, federal regulations allow an IRB to approve, (a) a waiver of consent, (b) a waiver to alter an element, or (c) a waiver of documentation of consent so long as certain criteria are met.

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| **SECTION H1: This request is to (*check all that apply*):** |

[ ]  **Waive the requirement to obtain informed consent [complete section H2 & H3]**

DoD regulations require that you obtain consent from subjects prior to data collection unless a waiver is approved by the IRB.*A waiver of consent is required if you do not intend to obtain consent.*

**Does the research involve experimental subjects?**

Research involving a human being as an experimental subject: An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction (DODI 3216.02).

[ ]  No

[ ]  Yes. Waiver requires Secretary of Defense approval (10 USC 980).

[ ]  **Alter the required elements of consent (use of deception)** **[complete section H2 & H3]**

If requesting waiver of an element, list the elements you wish to waive. For a listing of all elements see 32 CFR 219.116.

DOD regulations list 14 elements of informed consent that are required to be provided to subjects in the consent form script unless waived by the IRB**.** A waiver is required if the research involves deception.

[ ]  **Waive the requirement to obtain documentation of informed consent [complete section H2 & H4]**

DoD regulations require subjects to sign the consent form unless a waiver is approved by the IRB.*A waiver of documented consent is required if you plan to provide a consent form to subjects, subjects will read and acknowledge it, but will not sign a consent form (e.g., online survey, phone interview, etc.)*

**Waiver applies to the following subject populations:**

*Note: Please state if the waiver request is for all subjects or certain subject populations. For example, if your research involves only an online survey the waiver request will be for the entire population. If your research involves interviews, then the waiver request will only apply to subjects who participate over the phone.*

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| **SECTION H2:** Briefly explain why you are making this request and provide rationale. |

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| **SECTION H3:** Answer all A’s **OR** B’s for how your project meets each criterion for waiving or altering the consent process. |

A1. The research involves no more than minimal risk to the subjects;

[ ]  Yes

[ ]  No

A2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

[ ]  Yes

[ ]  No

A3. The research could not practicably be carried out without the waiver or alteration; and

[ ]  Yes

[ ]  No

A4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

[ ]  Yes

[ ]  No

[ ]  N/A

All four items (A1-A4) must be met and justified for the IRB to waive or alter the requirement of informed consent.

B1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials. **Note, this does not typically apply to NPS researchers.**

[ ]  Yes

[ ]  No. Waiver may not be granted.

B2. The research is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

[ ]  Yes

[ ]  No.

B3. The research could not practicably be carried out without the waiver or alteration.

[ ]  Yes

[ ]  No.

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| **SECTION H4:** Answer all A’s **OR** B’s for how your project meets each criterion for waiving the requirement to document consent. |

A1.Does the research present no more than minimal risk to the subject?

[ ]  Yes

[ ]  No. The research does not qualify for a waiver.

A2.Does it involve procedures for which written consent is normally required outside of the research context?

[ ]  Yes

[ ]  No

A3. The information to be presented to subjects (which must be provided in written form), includes all required and any additional elements of informed consent.

[ ]  Yes

[ ]  No

B1. Would the only record linking the subject and the research be the consent document?

[ ]  Yes

[ ]  No

B2. Would the principal risk be potential harm resulting from a breach of confidentiality?

[ ]  Yes

[ ]  No

B3. Will each subject be asked whether they want a signed copy of the consent form?

[ ]  Yes

[ ]  No

***Go to the Principal Investigator Statement of Assurance. PI must review and sign at the bottom of the signature page.***

**PART 2: RECORD OF PROTOCOL AMENDMENT**

Instructions: All modifications to approved protocols must be reviewed and approved by the IRB and NPS Institutional Official (if change in mission) before implementation, except when necessary to eliminate apparent immediate hazards to subjects. Examples of protocol modifications include but are not limited to changes in: subject populations, sample size, recruitment procedure, consent procedure, research design, data collection tools and research team personnel. Provide the information requested below (Date and Summary of Modifications), then go to Part 1 and update the Initial IRB Application information *using track changes*. Delete all *italicized* guidance before submitting to the IRB for review.

*Leave this page blank if submitting an Initial IRB Application or a Continuing Review.*

**Amendment** (to modify approved research)

1. Complete **PART 2: RECORD OF PROTOCOL AMENDMENT** and summarize the proposed modifications in the block(s) below.
2. **Use track changes** to modify **PART 1: RESEARCH PROTOCOL** according to your revised research plan. Amendments received without the use of track changes will be returned.
3. **Sign (or re-sign) the signature page at the end of this document.**
4. Attach all revised documents when applicable and submit completed documents to IRB@nps.edu.

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| **Review the following list of documents and determine if any of the proposed amendments will require modification**  |
| **CITI Ethics completion reports.***Needed for each new member of the research team.* |
| **Consent form** |
| **Recruitment script** *modifications* |
| **Data collection tools**, *if modified (survey, interview questions, questionnaire, etc.)* |
| **List of data variables**, *if modified (AARs, personnel records, training records, etc.*) |
| **Conflict of Interest Form** *signed by each new member of the research team.*  |
| **Scientific Review Form***Required if the research design or question has changed.*  |

**Date:**

**Summary of Modifications:**

All proposed changes must be specified in this section

**Date:**

**Summary of Modifications:**

All proposed changes must be specified in this section

*Sign (or re-sign) signature page at the end of this document—required for* ***every*** *amendment request.*

**PART 3: RECORD OF Continuing Review**

Instructions: Continuing review is required prior to the expiration of a protocol to extend the approval period. All interaction with subjects and analysis of data containing identifiable information must stop at expiration. (Note: Continuing reviews are no longer required for minimal risk research protocols. Only greater than minimal risk protocols and those expedited studies designated as requiring a continuing review in the Institutional Official approval letter (i.e. approved prior to common rule changes) will be required to submit a continuing review to extend the approval period.) If a Continuing Review is required, provide the information requested below (Questions 1 - 15), then go to Part 1 and update the Initial IRB Application information *using track changes*. Delete all *italicized* guidance before submitting to the IRB for review.

*Leave Part 3 blank if submitting an Initial IRB Application or an Amendment.*

**Continuing Review** (to extend approval period)

Complete **PART 3: RECORD OF PROTOCOL Continuing Review**

**1. Provide a brief research summary to include the objectives of the research, research plan/methods, and findings to date, including preliminary results.**

**2. Provide a summary of any new and relevant information, published or unpublished, that has become available since the last IRB review, especially information that may affect the IRB's deliberation about the risks and benefits associated with the research.**

**3. Summarize any problems encountered during the conduct of the research.**

**4. Total number of subjects approved by the IRB:**

**5. Total number of subjects enrolled in the research to date:**

A subject is considered enrolled after completing the consent process.

**6. Number of additional subjects to be enrolled:**

**7. Have any enrolled subjects withdrawn or been excluded from the study?**

[ ]  No

[ ]  Yes. Explain why below.

**8. Provide a summary of subject experiences and any complaints about the research since the last IRB review.**

**9. If vulnerable populations have been enrolled, describe the protections and if they are adequate.** Note: Vulnerable populations may include military, DOD civilians, children, prisoners, and pregnant women. If no vulnerable populations are enrolled state "NA" below.

**10. Provide a current risk to potential benefit assessment based on study results thus far.**

**11. Please describe what risks, side effects, or discomforts have been observed.** Consider physical, psychological, social, and economic risks.

**12. Describe any unanticipated problems involving risks to human subjects or others (UPIRTSO).** If no UPIRTSO's have occurred state "NA" below.

**13. Do (or have) any of the above risks require(d) modification to the research protocol (recruitment, consent, study design, etc.)?**

[ ]  No

[ ]  Yes. Briefly describe the modifications needed and amend **PART 3: INITIAL IRB APPLICATION** using track changes.

**14. Has the protocol expired?**

[ ]  No

[ ]  Yes. Explain why a lapse in approval occurred and indicate if research continued after expiration.

*Sign (or re-sign) the signature page at the end of this document.*

**Principal Investigator Statement of Assurance**

I certify that the information provided in this application is complete and accurate.

I understand that as the Principal Investigator (PI), I have ultimate responsibility for the conduct of the study, the activities of all other investigators listed on the protocol, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to the study protocol.

I understand that human subject research activities, including recruitment, may not commence until the Institutional Review Board (IRB) completes its review and, if determined not to be exempt, the Institutional Official (IO) approves.

I will not implement changes to approved research without IRB and IO approval except when necessary to eliminate apparent immediate hazards to the subject and will submit an amendment to the IRB within 5 business days.

I will inform the IRB Chair or Vice Chair, and the Medical Monitor (if one is assigned) of any unanticipated problems involving risks to subjects or others (UPIRTSOs) within 24 hours. I will submit a UPIRTSO report form to the IRB within 5 business days.

I have no conflict of interest preventing me from performing this research.

I will maintain all research records on file. Records include but are not limited to: approved initial review protocol/amendments/continuing reviews, CITI ethics training records for each member of the research team, correspondence with the IRB, research data and notes, consent forms, UPIRTSO reports, and research agreements.

I recognize that the IRB has the authority to observe (or have a third party observe) the consent process and the conduct of research, and to inspect all research records at any time.

I understand that a continuing review or research protocol check-in must be submitted in accordance with federal and institutional regulations and policies. The research must be reviewed by the IRB and approved by the IO before the expiration date or all research activities including interaction with subjects and personally identifiable data must stop.

I understand that I must submit a final report to the IRB upon expiration of the protocol for all non-exempt research. Notification of study closures to the IRB for exempt studies should be submitted through a research protocol check-in.

I have read, understand, and agree to follow the NPS Instruction on the Protection of Human Subjects.

Principal Investigator Signature:

*This document must be digitally signed.*

1. *Save the document as a Word File.*
2. *Convert the document to a pdf.*
3. *Add your digital signature to this page and save the pdf.*
4. *Use the saved Word file if you need to submit amendments or continuing reviews to the IRB.*

**Submit this form along with finalized copies of all project related materials.**

**Include the following when required:**

|  |
| --- |
| **CITI ethics completion reports for each researcher.** *Registration instructions:* [*https://my.nps.edu/web/research/irb-ethics\_training*](https://my.nps.edu/web/research/irb-ethics_training) |
| **Research proposal** (thesis proposal, funded SOW, etc.) |
| **Consent form**  |
| **Recruitment script**  |
| **Data collection tools**, *if applicable (survey, interview questions, questionnaire, etc.)* |
| **List of data variables**, *if requesting use of pre-collected data (AARs, personnel records, training records, etc.)*  |
| **Conflict of Interest Form** *signed by each member of the research team.*  |
| **Scientific Review Form** *Not required for exempt research* |
| **Evidence of Support from outside institutions/commands** *permission from military facilities or units in which recruitment will occur or the study will be conducted* |

IRB Forms and Templates: <https://my.nps.edu/web/research/irb-forms>

***Submit the study package for review by email to*** ***irb@nps.edu******.***

Note, no human subject research in any form (including recruitment, consent, or data collection) can take place without proper review and approval by the NPS IRB and NPS President.

**IRB Review Process**