**This form is to be used for Initial IRB Applications (Part 1), Amendments (Parts 1 and 2), and**

**Continuing Reviews (Parts 1 and 3),**

**OVERVIEW AND PROTOCOL CHECKLISTS**

This 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.

1. **Initial IRB Application** (for new research)
2. Complete **PART 1: RESEARCH PROTOCOL**
3. Complete the documents below.
4. Sign (or re-sign) signature page at the end of this document.
5. Submit completed documents to [IRB@nps.edu](mailto:IRB@nps.edu).

|  |  |
| --- | --- |
|  | **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**  *Not required for exempt research or for research involving only archival records*. |
|  | **Recruitment script**  *Not required for exempt research or for research involving only archival records*. |
|  | **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.* |

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

1. **Amendment** (to modify approved research)
2. Complete **PART 2: RECORD OF PROTOCOL AMENDMENT**
3. **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.
4. Sign (or re-sign) signature page at the end of this document.
5. Attach all revised documents when applicable and submit completed documents to [IRB@nps.edu](mailto: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.* |

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

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

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 will be required to submit a continuing review to extend the approval period. All other minimal risk studies will be asked to complete an annual protocol check-in (APC) with the NPS Human Research Protection Program (HRPP) office. The APC request will be initiated by the HRPP office.

1. **Part 4: EXEMPT CATEGORES AND ELEMENTS OF CONSENT**

**Part 4** provides additional information for investigators, specifically, exempt categories and elements of consent.

**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** |

**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.

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator**  **(The PI for student research is the advisor)** | | | |
| Name | Title or Rank | Department or Org Name | Investigator  Roles and Responsibilities |
|  |  |  |  |
| **Co-Investigators and Student Investigators** | | | |
| Name | Title or Rank | Department or Org Name | Investigator  Roles and Responsibilities |
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**3.** **Estimated completion date of the research:**

If student research, list student graduation date.

**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?**

A description of the exempt categories is provided at the end of the protocol. If requesting an exempt review, the following documents are not required:

- Scientific Review Form

- Recruitment Script

- Consent Form

If determined "not exempt" by the IRB, the above documents will be required.

No

Yes. List category #:

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

**6. 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.”*

**7. Describe the research study design**.

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

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

*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 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, type N/A in the box.*

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

*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.*

**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)?**

Example 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.*
* *If the records are provided in a table, list or attach on a separate page listing the variables provided in the records.*
* *State where the records are currently located.*
* *State the number of unique individuals represented in the records you will access.*

**11b. 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.

**11c. For what purpose will these secondary information or biospecimens be used?**

To collect data that will be analyzed in the research.

To identify potential subjects.

Other. Describe below.

**12. 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 inherent controversial topics (those likely to attract media coverage or challenge 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 and Recruitment** |

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

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| --- | --- | --- | --- |
|  | 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 |  |  |

**14. 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.*

**15. 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 biospecemins, place a "0" in the box.*

**16. 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. Reference DoDI 3216.02 for guidance on compensating research subjects.*

**17. 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.*

**18. 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 in order to obtain compliance. Undue influence occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. Consider the following:*

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

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| **D.** **Risks and Benefits** |

**19. 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 |  |
|  |  |  |  |

**20. 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 Q19.*

**21. Explain what steps will be taken to minimize risks and discomforts (mentioned in Q19-20) and to protect subjects' welfare.**

*Include a plan to minimize all risks mentioned in Q19-20.*

**22. Provide a description of 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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| **E.** **Data Security & Monitoring** |

**23. Will you 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 name 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 Q23.*

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

No

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

*Describe in detail what will be recorded, why you need to record and how the data will be stored and safeguarded. Please note that recordings cannot be deleted unless transcribed.*

**25. 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 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 10 years before forwarding to a federal record center.*

**26a. When appropriate, a research plan is required to make adequate provisions for monitoring the data to ensure 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*.

**26b. Will the study include collection of surveys or questionnaires?**

No

Yes. Describe your procedure for monitoring the number of surveys and/or questionnaires collected to ensure no more than the approved number is collected.

*Include the following:*

* *How often will you check the number of surveys/questionnaires collected (i.e. daily, twice a week, weekly).*
* *At what point will you stop collecting responses and what steps must be taken to stop collection. For example, an online survey link can be disabled. If subjects are submitting through a drop box that drop box would be removed.*
* *Note: Report all overcollections to the IRB via* [*IRB@nps.edu*](mailto:IRB@nps.edu) *as soon as possible.*

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| **F. Biospecimen Collection** |

**27. Will your research involve collection or analysis of saliva or other biospecimens?**

No. Skip to G. Consent Procedure.

Yes, saliva only.

Yes, saliva and/or other types of biospecimens. Explain below.

**28. Describe the biological measures being taken and what hormones/biomarkers are being investigated.**

**29. Describe the method of collection (e.g. passive drool, swab, etc.) and state when re-sampling may be required (e.g. visible blood, discoloration, etc.).**

**30. Describe the level of discomfort associated with the chosen sampling method.**

**31. Are you collecting samples using third party sample collection kit? *If yes, attach a copy of the kit instructions and provide justification for any deviation from the recommended procedure.***

**32. List the characteristics of the participants from whom the biospecimens to be collected.**

**33. State what information will be listed on the sample labels and how samples will be identified.**

**34. State how you will maintain participant confidentially and privacy during transport and storage. Describe your procedure for packaging and shipping specimens from the collection site to storage site at NPS.**

**35. State where samples will be analyzed.**

**36. Provide the timeline and procedure for sample destruction.**

**37. Will collection for a sub-study occur? If yes, list IRB approval number for each sub-study.**

**38. Describe scenarios in which subjects may be contacted in the future and the timeline for contact (e.g., provide incomplete/missing information, request second sample due to sample inadequacy, etc.).**

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| **G. Consent Procedure** (If requesting exempt review skip to Q41) |

**39a. DoD regulations require that you obtain consent from subjects prior to data collection unless a waiver is approved by the IRB. Are you requesting a waiver of consent?** *A waiver of consent is required if you do not intend to have subjects read and sign a consent form.*

No

Yes.

**39b. DoD regulations require subjects to sign the consent form unless a waiver is approved by the IRB. Are you requesting a waiver of signed consent?** *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.)*

No

Yes

**39c. DOD regulations require that you provide a consent document to subjects (electronically or in hard copy) unless waived by the IRB. Are you requesting a waiver from the requirement to provide subjects with a consent form?**

No

Yes

**39d. 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. Are you requesting to exclude any of these elements?** A waiver is required if the research involves deception.

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

No

Yes

**41. 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.

*Consent is a process. 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.)?*

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| **H. Consent Waivers.**  **-** Not required for exempt studies.  - Complete if you check “yes” to Q39a, b, c, and or d. |

**42a. Are you requesting a waiver of documented consent** (checked “Yes” to 39b or 39c)**.**

No. Skip to Q43.

Yes

**42b. Check the appropriate waiver request type(s).**

Waive the requirement to collect a signature on the consent form.

Waive the requirement to provide subjects with a consent form.

**42c.** **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 will 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.*

**Waiver Criteria**

**To be approved, waiver criteria found in 42d or 42e must be affirmative.**

**42d. Does the research meet the following criteria?**

* The research involves no more than minimal risk to subjects.
* Research involves no procedures for which written consent is normally required outside the research context.
* The information to be presented to subjects (which must be provided in written form as part of the IRB application), includes all required and any additional elements of informed consent.

No.

Yes. Skip to 43.

**42e. Does the research meet the following criteria?**

* The only record linking the subject and the research is the consent document.
* Each subject will be asked whether he or she wants documentation linking the participant with the research, and the subjects' wishes will govern.
* The information to be presented orally to subjects (which must be provided in written form as part of the IRB application) includes all required and any additional elements of informed consent.

No. The research does not qualify for a waiver of documented consent.

Yes

**43a. Are you requesting a waiver of consent or elements of consent** (checked “Yes” to 39a or 39d)**?**

No. Skip to H. Principal Investigator Statement of Assurance

Yes.

**43b. 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).

**43c. Is the research regulated by the FDA?**

No

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

**43d. Check the appropriate waiver request type(s).**

Waive the requirement to collect consent.

Waive one or more elements of informed consent (use of deception). If requesting waiver of an element, list the elements you wish to waive. For a listing of all elements see 32 CFR 219.116.

**43e. 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 use of pre-collected data (personnel records, training records, lessons learned, etc.) this request would be for all persons represented in the data set*.*

**Waiver Criteria**

**To be approved, waiver criteria found in 43f or 43g must be affirmative.**

**43f. Does the research meet the following conditions?**

* The research involves no more than minimal risk to subjects. Minimal risk means that the probability and magnitude of harm or discomfort anticipated is not greater in and of themselves than those ordinarily encountered in daily life.
* The waiver or alteration will not adversely affect the rights and welfare of subjects by not obtaining consent.
* The research cannot practicably be carried out without the waiver or alteration.
* When appropriate, the subjects will be provided with additional pertinent information after participation.

No.

Yes. Skip to H. Principal Investigator Statement of Assurance

**43g. Does the research meet the following conditions?**

* The research is conducted by or subject to the approval of state or local government officials.
* The research is designed to study, evaluate, or otherwise examine:
  + Public benefit or service programs
  + Procedures for obtaining benefits or services under those programs
  + Possible changes in methods or levels of payment for benefits or services under those programs
  + The research cannot practicably be carried out without the waiver or alteration.

No. Waiver may not be granted.

Yes

*Sign signature page at the end of this document.*

**PART 2: RECORD OF PROTOCOL AMENDMENT**

Instructions: All modifications to approved protocols must be reviewed and approved by the IRB and NPS Institutional Official 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 bank if submitting an Initial IRB Application or a Continuing Review.*

**Date:**

**Summary of Modifications:**

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

**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 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.*

**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 come 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 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 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 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.

**15. Has the protocol expired?**

No

Yes. Explain why a lapse in approve occurred and indicate if research continued after expiration.

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

**PART 4: EXEMPT CATEGORIES AND ELEMENTS OF CONSENT**

**Exempt Categories** (as of 21 Jan 2019)

(1) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, *and an IRB conducts a limited IRB review to make the determination required* by § 219.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, *and an IRB conducts a limited IRB review to make the determination required* by § 219.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use *if an IRB conducts a limited IRB review and makes the determinations required* by § 219.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 219.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 219.117;

(iii) *An IRB conducts a limited IRB review and makes the determination required* by § 219.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

**Sixteen Elements of Consent (32 CFR 219.116, 2018)**

(All are required unless a waiver is granted)

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(6) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(7) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(8) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

(9) A description of any reasonably foreseeable risks or discomforts to the subject.

(10) A description of any benefits to the subject or to others that may reasonably be expected from the research.

(11) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(12) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

(13) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(14) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(15) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(16) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**Nine Additional Elements of Consent (32 CFR 219.116, 2018)**

(To be included if/when appropriate)

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing ( i.e.,sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Signature Page**

**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 of 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.

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. *Email the pdf to* [*irb@nps.edu*](mailto:irb@nps.edu) *.*
5. *Use the saved Word file if you need to submit amendments or continuing reviews to the IRB.*