**DEPARTMENT OF DEFENSE (DOD) SUPPORTED RESEARCH SUPPLEMENTAL FORM**

PI:

Protocol Title:

The following items/documentation is required for research supported and/or regulated by the Department of Defense (DOD). For any items that pertain to your research (i.e. marked “yes”), please verify that the appropriate protections are in place. Provide comments as instructed or as necessary.

**Definitions & Associated Guidance**

**DOD Component:** means the Office of the Secretary of Defense, a Military Department, a Defense Agency, a DoD Field Activity, or any other organizational entity of the Department of Defense that is authorized to award or administer grants, cooperative agreements, or other non-procurement transactions.

**DOD Personnel**: includes military service members and civilian employees who are under the authority of the DoD.

The definition of **minimal risk** based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

**Research involving an experimental participant** is defined as 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*. Research involving a human being as an experimental participant is a subset of research involving human participants. This definition relates only to the application of section 980 of Reference (g); it does not affect the application of part 219 of Reference (c). This definition does not include activities that are not considered research involving human participants, activities that meet the exemption criteria at section 219.101(b) of Reference (c), and research involving the collection or study of existing data, documents, records, or specimens from living individuals.

In general:

* Department of Defense research involving a human being as an experimental participant must obtain the prior informed consent of the participant.
* Research with prisoners of war is prohibited. Investigators should refer to the definition of “prisoner of war” for the particular DoD component supporting the research.

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| **Section I: General** |
| 1. [ ] Yes [ ]  No
 | Are you conducting non-exempt human research involving classified information?If YES 🡪 [ ]  confirm that the research follows the requirements of [3216.02 13](https://www.ncbi.nlm.nih.gov/books/NBK236819)*Please note: The review of research involving classified information is rare and requires Secretary of Defense approval and the IRB will need to be informed of status of this approval.* |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does the research require additional training due to any DOD components?*NOTE: DOD may require human research protections training every 3 years.* If YES 🡪 In the comments below, please verify what additional training was completed and by which members of the study team. |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Are you conducting human research involving the testing of chemical or biological agents? NOTE: This research is prohibited with limited exceptions for research on prophylactic, protective, or other peaceful purposes. Exceptions require approval by the DoD Office for Human Research Protections (DOHRP). **Chemical agents** (a chemical substance that is intended for use in military operations to kill, seriously injure, or incapacitate a person through its physiological effects. Excluded from consideration are riot control agents, chemical herbicides, smoke, and flame). **Biological agents** (the term “biological agent” means any micro-organism (including bacteria, viruses, fungi, rickettsia, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, that is capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; or deterioration of food, water, equipment, supplies, or materials of any kind; or deleterious alteration of the environment.[ ]  Written approval from DOHRP is provided. |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Are you conducting human research that enrolls DOD Personnel (military service members OR civilian employees)? IF YES 🡪 Complete Section III Human Research with DOD Personnel |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Are you conducting human research that enrolls and vulnerable populations? IF YES 🡪 Complete Section IV: Human Research with Vulnerable Populations |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Is the research international?IF YES 🡪 The Investigator must abide by local laws, regulations and customs, as applicable. Indicate local ethics approval status: [ ]  Documentation of local approval included in the submission[ ]  Documentation of local approval is pending[ ]  Local review and approval is not required. 🡪 *Please explain below.*[ ]  Local review and approval is not possible 🡪 *Submit a letter to the IRB explaining why local review is not possible.* |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does the research involve compensation (remuneration)? IF YES 🡪 [ ]  Confirm that participants will be compensated for research participation other than blood draws (see below) in a reasonable amount as approved by the IRB.1. Does the research involve blood draws?

[ ]  No[ ]  Yes 🡪 [ ]  Please confirm that individuals will not be compensated more than $50 per blood draw. |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Will the research be conducted at multiple sites? IF YES 🡪 Will the University of Pennsylvania be the lead site?[ ]  No 🡪 [ ]  Please confirm by checking the box that the University of Pennsylvania site has received and signed a copy of the agreement/statement of work or will receive this document prior to initiating any study procedures at this site.[ ]  Yes 🡪 The Investigator must execute an agreement or statement of work with all collaborating sites that delineates each site’s responsibilities. This document should include the following elements: [ ]  A brief description of the research [ ]  Specific roles and responsibilities of each site, including scientific and IRB review; recruitment of participants; and informed consent procedures[ ]  Plan for ongoing data and safety monitoring, reporting requirements, documentation retention, and compliance for the entire research project[ ]  Agreement/statement of work is included in the application.  |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Is this emergency medicine research? IF YES 🡪 [ ]  The Principal Investigator has obtained approval from the DOHRP for a waiver of the advance informed consent provision of [10 USC 980](https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section980&num=0&edition=prelim).  |
|  Comments |       |
|  | **DOD Reporting Responsibilities**The following shall be promptly reported (no longer than within 30 days) to DOD human research protections officer:* When significant changes to the research protocol are approved by the IRB
* The results of the IRB continuing review
* Change of reviewing IRB
* Reports of audits of DoD-conducted or DoD-supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government.
* Study Closure

[ ]  Please confirm by checking the box that the Principal Investigator accepts this additional reporting responsibility |
|  Comments |       |

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| **Section II: Informed Consent** |
| 1. [ ] Yes [ ]  No
 | Does the research involves prospective informed consent? **IF NO** 🡪 Please confirm one of the following: [ ]  The research is exempt research; OR[ ]  The research **does not** involve an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction; OR[ ]  A waiver was obtained from the Assistant Secretary of Defense for Research and Engineering because: 1) the research is necessary to advance the development of a medical product for the Military Services, 2) may directly benefit the individual experimental subject, and 3) is conducted in compliance with all other applicable laws and regulations. **The application includes a copy of the waiver approved by the Assistant Secretary of Defense for Research and Engineering.****IF YES** 🡪 Prospective informed consent will be obtained: 1. Confirm the consent document includes:

[ ]  A statement that the DoD or a DoD organization is funding the study.[ ]  A statement that representatives of the DoD are authorized to review research recordsFor greater than minimal risk research –*OR Check if N/A [ ]* [ ]  A statement how organizations will care for participants with research-related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel in studies that are collaborative with a non-DoD institution.1. Does the consent process involve a legally authorized representative for participants with impaired consent capacity?

[ ]  No[ ]  Yes 🡪 Explain how the research is intended to provide direct benefit to the individual participant:      .**The IRB must determine that the intent of the research is to benefit the individual experimental subject prior to execution of this consent process.**  |
|  Comments |       |

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| **Section III: Human Research with DOD Personnel** |
|  | Please identify which groups will be enrolled (check all that apply) [ ]  U.S. military personnel [ ]  DOD Personnel |
| 1. [ ] Yes [ ]  No
 | Are you performing surveys on DOD personnel?IF YES 🡪 Note that the surveys must be submitted, reviewed and approved by the DoD Information Management Control Officer (IMCO) after approval by the IRB. Enrollment may not commence until this approval is provided to the IRB.  When a survey crosses DoD components, additional review may be required; please consult with DoD to confirm that all appropriate reviews/approvals have been obtained. [ ]  Confirm that upon approval by the DOD, this approval will be submitted to the IRB via a modification. |
|  Comments |       |
| 1. [ ] Yes [ ]  No

[ ]  N/A military personnel are not enrolled | Is there prospective recruitment of military personnel? IF YES 🡪 1. Please confirm all of the following are in place:

[ ]  Officers will not be permitted to influence the decision of their subordinates.[ ]  Officers and senior non-commissioned officers may not be present at the time of recruitment.[ ]  Officers and senior non-commissioned officers will have a separate opportunity to participate.1. Will recruitment occur in a group setting?

[ ]  No[ ]  Yes 🡪 If the research is greater than minimal risk, the IRB is required appoint an ombudsperson that does not have a conflict of interest with the research, nor be a part of the research team. For minimal risk research, the IRB may consider requiring an ombudsperson |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does the research involve compensation (remuneration)? IF YES 🡪 1. Please confirm that research participation does not occur while the U.S. military personnel is on duty.

[ ]  Confirmed[ ]  N/A military personnel are not enrolled |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does the research involving collecting genomic data from DoD-affiliated personnel?IF YES 🡪 1. Please confirm the following:

[ ]  Due to the risk to national security, the written materials describe administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.1. Does the research involve large-scale genomic data collection?

[ ]  No[ ]  Yes 🡪 Please confirm the following: [ ]  A certificate of confidentiality from DHHS has been obtained[ ]  DoD component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards has been obtained. If not yet obtained, please describe when it is anticipated:       |
|  Comments |       |
|  | If the research involves prospective informed consent, confirm the consent document includes the following additional required elements. –*OR Check if N/A [ ]* [ ]  *If the research involves risks to their fitness for duty (e.g., health, availability to perform job, data breach),* the informed consent informs DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.[ ]  *If applicable*, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty.For greater than minimal risk research –*OR Check if N/A [ ]* [ ]  A disclosure that participants may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants’ participation in the study to such time after the study has ended. |
|  Comments |       |

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| **Section IV: Human Research with Vulnerable Populations** |
| 1. [ ] Yes [ ]  No
 | Does the research target Pregnant Individuals for enrollment?IF YES 🡪 Note the following:* For purposes of applying Subpart B, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge”.
* The applicability of Subpart B is *limited to* research involving pregnant individuals as participants in research that is *more than minimal risk* and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

[ ]  Confirm the Research with Pregnant Individuals, Fetuses, And Neonates Supplemental Form is included in the application.   |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does this research involve research with human fetal tissue? IF YES 🡪 [ ]  Confirm the research complies with the [US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g](https://www.law.cornell.edu/uscode/text/42/289g-1#:~:text=Go!-,42%20U.S.%20Code%20%C2%A7%20289g%E2%80%931%20%2D%20Research,on%20transplantation%20of%20fetal%20tissue&text=The%20Secretary%20may%20conduct%20or,fetal%20tissue%20for%20therapeutic%20purposes). [ ]  Confirm the Research with Pregnant Individuals, Fetuses, And Neonates Supplemental Form is included in the application.  |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does this research target incarcerated persons (including detainees) for enrollment OR request to allow a participant who becomes an incarcerated person to remain on study?IF YES 🡪 Please specify: [ ]  The research targets incarcerated persons for enrollmentIs the person a detainee? [ ]  No[ ] Yes 🡪 Does the research involve investigational drugs or devices that would be offered to US military personnel in the same location for the same condition?[ ]  No🡪 The research is prohibited.[ ]  Yes[ ]  This is a request to allow a participant who became incarcerated person to remain on study 🡪 [ ]  The PI understands all research interactions and interventions with the incarcerated person-participant (including obtaining identifiable private information) must cease, unless an exception is otherwise granted by the IRB chair pending convened review of this request. [ ]  A letter has been included for board consideration explaining: * + - How remaining on the study is in the best interest of the incarcerated person,
		- How the rights and wellbeing of the incarcerated participant are not in jeopardy
		- The incarcerated participant can continue to consent to participate
		- The incarcerated participant is capable of meeting the research protocol’s requirements.
		- The terms of the participant’s confinement does not inhibit the ethical conduct of the research
		- There are no other significant issues preventing the research involving human participants from continuing as approved

[ ]  Confirm the Research with Incarcerated Persons Supplemental Form is included in the application. |
|  Comments |       |
| 1. [ ] Yes [ ]  No
 | Does this research involve viable neonates or other minors (children)? IF YES 🡪 Note the following:* Research involving children cannot be reviewed at the exempt level unless it is restricted to research involving observations of public behavior AND the investigator(s) do not participate in the activities being observed.
* DoD requirements for obtaining consent from individuals with impaired consent capacity applies to research with children.

[ ]  Confirm the Research with Children Supplemental Form is included in the application.  |
|  Comments |       |

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| **Section V: SIGNATURE** |
| Principal Investigator | Signature:       Date:      **Typing your name above serves as your signature and confirmation that the information in this form is accurate.**  |

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| **IRB OFFICE ONLY** |
| IRB Administrator | **NOTE: Refer to SOP DD 100 for determinations that the IRB may need to make. Enter name below to confirm these are/will be addressed.** Signature:       Date Screening Completed:        |