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| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

**Instructions:**

Complete this form and attach it in Hutch IRB if the research involves funding, facilities, data, or personnel from the Department of Defense (DoD) or one of its component entities (e.g., Dept. of Army, DARPA).

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|  | Diagram  Description automatically generated | **FORM - Department of Defense (DoD) Supplement** |

1. Which component(s) of the United States Department of Defense (DoD) are involved in this research? *Check all that apply:*

[ ]  Department of the Navy

[ ]  Office of Naval Research

[ ]  U.S. Naval Observatory

[ ]  Naval Academy

[ ]  Department of the Army

[ ]  U.S. Army Corps of Engineers

[ ]  Military Academy (West Point)

[ ]  Department of the Air Force

[ ]  Air Force Academy

[ ]  Marines

[ ]  Coast Guard

[ ]  National Guard

[ ]  Missile Defense Agency

[ ]  Defense Advances Research Projects Agency (DARPA)

[ ]  Pentagon Force Protection Agency

[ ]  Defense Intelligence Agency

[ ]  National Geospatial-Intelligence Agency

[ ]  National Security Agency

[ ]  Under Secretary of Defense (Personnel and Readiness) – Note extra training requirements in Question 3.7

[ ]  Other:

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2. How is the Department of the Defense (DoD) component involved in your research? *Check all that apply:*

[ ]  The research is funded by a component of DoD (for example, by the Office of Naval research).

[ ]  The research involves cooperation, collaboration, or other type of agreement with a component of DoD. Example: An Army Medical Laboratory will conduct tests on the blood samples you collect in your study.

[ ]  The research uses property, facilities or assets of a component of DoD. Example: Madigan Hospital

[ ]  The subject population will intentionally include personnel (military and/or civilian) from a component of DoD, or data or specimens from DoD personnel.

3. Research involving Department of Defense Components – Restrictions and Additional Requirements. Respond to all of the following:

3.1. During the research will you administer surveys or questionnaires, or do interviews with, DoD personnel or their families?

[ ]  Yes → Most DoD components have specific language and administration requirements related to survey, questionnaires and interviews with DoD personnel. Consult with your DoD component agency and respond to one of the following:

[ ]  I have been advised that additional survey/interview approval by the DoD component is not required. 

[ ]  I have submitted documentation of the DoD component’s approval of the survey/interview.

[ ]  I have been advised by the DoD component to obtain IRB approval first, and then submit the survey/interview for approval by my DoD component. 

[ ]  Other discussion or result → Describe below:

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[ ]  No

3.2. Does this research involve subjects who cannot provide consent for themselves (e.g., children, or adults with impaired decision-making capacity)?

[ ]  Yes → Per DoD Instruction 3216.02 section 3.11.c. if a subject cannot consent for themselves, the IRB must determine that the research is intended to be beneficial to the individual subjects. Describe the benefits expected for individual subjects:

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[ ]  No

3.3. Does this research involve the recruitment of [DoD-affiliated personnel](https://extranet.fredhutch.org/u/irb/glossary.html#dod-personnel) into more than [minimal risk](https://extranet.fredhutch.org/u/irb/glossary.html#minimal) research?

[ ]  Yes → Go to Question 3.3.a.

[ ]  No → Go to Question 3.4.

3.3.a. Per DoD Instruction 3216.02 section 3.9.f for research involving more than minimal risk, if DoD-affiliated personnel will be recruited into the research the research team must ensure special protections are in place as follows:

* An individual’s decision about participation has not been influenced by military and civilian supervisors, officers, and others in the chain of command;
* Military and civilian supervisors, officers, and others in the chain of command are excluded from solicitation/recruitment/consent sessions for units under their command;
* Separate recruitment/consent sessions are offered for supervisors or those in the chain of command who were excluded from sessions held for their units; and
* An ombudsperson not connected in any way to the research or to the unit will be present at group recruitment briefings to monitor that the voluntary nature of individual participation is adequately stressed and that the information provided about the research is adequate and true. The ombudsperson will be available to address personnel’s concerns about participating in the research.
* The informed consent document informs DoD-affiliated personnel about any risks to their fitness for duty (e.g., health, availability to perform job, data breach), and that they should seek command or component guidance before participating. The informed consent document must also include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.
* If large-scale genomic data is being collected for the study, a Certificate of Confidentiality (CoC) has been obtained for the study, and CoC language has been added to the consent form.

Does the research include these additional protections for DoD-affiliated personnel?

[ ]  Yes

[ ]  No → Explain:

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3.4. Does this research involve a Department of the Navy Component (e.g., Navy, Marines)?

[ ]  Yes → Secretary of Navy Instruction 3900.39D, Section 8(c)(6) requires the IRB to have documentation of independent review and approval for scientific merit or scholarship (including a summary of scientific issues raised and addressed during the review). Indicate below who has completed the independent scientific review. For clinical research, Fred Hutch Scientific Review Committee or NIH peer review is satisfactory. For non-clinical, minimal risk, or exempt research, review by the Fred Hutch department head is sufficient. Submit a summary of the evaluation and findings with this supplement form. 

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[ ]  No

3.5. Is this research more than minimal risk (i.e., Full Review) and does it involve a Department of the Navy Component (e.g., Navy, Marines)?

[ ]  Yes → Secretary of Navy Instruction 3900.39D, Section 6(5) requires, for research involving greater than minimal risk, an arrangement for emergency treatment and necessary follow-up of any research-related injury. Describe the emergency treatment plan.

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[ ]  No

3.6. Does this research involve a Department of Navy component, and the research will be conducted outside the United States?

[ ]  Yes → Secretary of Navy Instruction 3900.39D, Section 6(i) research involving human subjects who are not U.S. citizens or DoD personnel, conducted outside the United States, and its territories and possessions, requires permission of the host country. Please describe below the ethics review undertaken by an IRB in the host country, or the local Navy IRB in the host country. Submit documentation of local host country IRB approval to conduct this research (note, this should also be reported on your coordinating center supplement form). 

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[ ]  No

3.7. Does your research fall under the purview of the Under Secretary of State (Personnel and Readiness)?

[ ]  Yes → Health Affairs (HA) Policy 05-003 requires that for research involving a DoD component under the purview of the Under Secretary of State (Personnel and Readiness) that all investigators and research staff directly involved in human subjects research shall have ***Annual*** training on human subjects protections. This requirement is more stringent than the Fred Hutch policy of retraining every 3 years. Describe how you will ensure you and the other research team members directly involved in the research maintain annual training on Human Subject protections.

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[ ]  No

3.8. Does this research involve compensation to active-duty military personnel for participation in the research?

[ ]  Yes → Go to Question 3.8.a.

[ ]  No → Go to Question 3.9.

3.8.a. Per the Dual Compensation Act, U.S. military personnel may not receive compensation for research while on active duty hours. This prohibition applies to U.S. military personnel paid from either appropriated or non-appropriated funds, or a combination thereof, and includes temporary, part-time and intermittent appointments. U.S. military personnel may be compensated for research if the participant is involved in the research while not on duty. If the research involves compensation for blood donations, 24 USC 30, further limits compensation to $50 per blood draw.

Does the research comply with these limitations?

[ ]  Yes

[ ]  No → Explain:

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3.9. Does this research comply with Department of Defense Instruction 3216.02 section 3.9.e, which prohibits research involving detainees and prisoners of war? This includes any person captured, detained, held, or otherwise under the control of DoD personnel (military and civilian, or contractor employee) except DoD personnel held for law enforcement purposes.

[ ]  Yes

[ ]  No → Explain:

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3.10. Are you requesting a waiver of consent for research meeting the Department of Defense Instruction 3216.02 definition of “[Research Involving a Human Being as an Experimental Subject](https://extranet.fredhutch.org/u/irb/glossary.html#research-involving-humans)”? This would include any non-exempt research involving an intervention or interaction with a human subject, regardless of research risk.

[ ]  Yes → Go to Question 3.10.a.

[ ]  No → Go to Question 3.11.

3.10.a Per 10 USC 980(b), and Department of Defense Instruction 3216.02 section 3.11.e, a waiver of consent for research involving a human being as an experimental subject must be approved by the Assistant Secretary of Defense for Research and Engineering, or the head of the DoD component involved in the research.

Has this approval been granted?

[ ]  Yes → Submit documentation of approval 

[ ]  No → Explain:

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3.11. Is this “emergency medicine research” as defined by Food and Drug Administration regulation 21 CFR 50.24?

[ ]  Yes → Explain and see [*HRP-023 - POLICY - Emergency Use or Compassionate Use of an Investigational Drug or Device*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#emergencyuse).

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[ ]  No