Institutional Review Board
THE UNIVERSITY OF UTAH

DEPARTMENT OF DEFENSE (DOD) SUPPLEMENT

Instructions

Research conducted or supported by a DoD Component requires additional information to be submitted to the IRB with the research application. This supplement serves as a checklist to ensure that additional requirements as outlined in DOD Directive 3216.02 are addressed by both the investigator and the IRB. Investigators must complete and attach this supplement to the Documents and Attachments page of the ERICA application. The investigator should retain this supplement for reference.

Additionally, investigators should be informed of the specific requirements for research that is conducted or supported by a DoD Component (e.g., through a contract, grant cooperative agreement or other arrangement).

Definitions

- The definition of **minimal risk** in 32 CFR 219, does not include the inherent occupational risks that certain subjects face in their everyday life, such as those: 1) encountered by service members, law enforcement, or first responders while on duty; 2) resulting from or associated with high-risk behavior or pursuits; 3) experienced by individuals whose medical conditions involve frequent tests or constant pain.

- **Prisoners of War:** POWs include any person captured, detained, held or otherwise under the control of the DoD personnel (military and civilian or contractor employee) including enemy prisoners, civilian internees, retained persons and lawful and unlawful combatants. Such persons do not include DoD personnel being held for law enforcement purposes.

- **Research involving a human being as an experimental subject** is 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.

Limitations and Prohibitions

- **Experimental Subjects:** Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates to the application of Section 980 of Title 10, U.S.C. and places certain limitations on waiver of informed consent and the use of a legally authorized representative (LAR). The limitations are outlined in the DOD Directive 3216.02. See questions 5 and 6.

- **Prisoners of War:** Research with detainees or prisoners of war (POW) is prohibited. See question 9.

- **Classified Research:** The University of Utah does not conduct or permit its faculty to conduct classified or secret research at the University or under a grant administered by the University. See question 10.

IRB Number:

PI:

Study Title:

Checklist

1. **How is the Department of Defense (DoD) involved in your research?** Check all that apply and specify the DoD component (e.g. The research is funded by the Department of the Army).

   ☐ Research is funded by _____

   ☐ Research involves cooperation, collaboration, or another type of agreement with _____
   _____

   ☐ The research uses property, facilities, or assets of
   _____

   ☐ The subject population will intentionally include personnel (military and/or civilian) or data or specimens from personnel from _____

2. **Have you a) verified the human subjects research training requirements of the DoD component related to your research and b) provided a plan to the IRB for ensuring completion and maintenance of the appropriate training by members of the research team directly involved in human subjects research?**

   ☐ **No** *Your application will not be approved until you have verified the required training and a plan is provided to the IRB to complete and maintain human subjects research training.*

   ☐ **Yes** *Describe the plan to ensure completion and maintenance of human subjects research training in the ERICA application on the Roles and Responsibilities page. Attach the research training requirements and any completed training certificates to the Documents and Attachments page in the ERICA application.*

3. Does the research involve the recruitment and enrollment of DoD-affiliated personnel as participants in research?

☐ **No** *Go to question 4.*

☐ **Yes**

a. If yes, does the research comply with the following guidelines?

- Officers are not permitted to influence the decision their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsperson will be present to monitor that the voluntary nature of participation is stressed and that the information provided is adequate and true.

☐ **No** *Your application will not be approved until you have complied with the required guidelines (above) for recruitment and enrollment of U.S. military personnel as participants in research.*

☐ **Yes** *Please ensure all the stipulations above are clearly outlined on the Consent Process page of your application. If your study involves greater than minimal risk, the IRB will appoint the independent ombudsperson as described above. If your study involves minimal risk, the IRB will determine whether an ombudsperson should be appointed. The decision to require the appointment of an ombudsperson should be based in part on the human subject population, the consent process, and the recruitment strategy.*

4. Does the research involve the compensation of U.S. military personnel as participants in research?

☐ **No** *Go to question 5.*

☐ **Yes**

a. If yes, does the research comply with the following guidelines?

- Participants may be compensated for research participation as long as the participant is involved in the research when not on duty. Enrolled individuals may not receive payment of compensation for research participation during duty hours.
- Federal employees while on duty and non-Federally employed individuals may be compensated for blood draws for research up to $50 for each blood draw.
- Non-Federally employed individuals may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB.

☐ **No** *Your application will not be approved until you have complied with the required guidelines (above) for recruitment and enrollment of U.S. military personnel as participants in research.*

☐ **Yes**

5. **Do you plan to obtain consent using a legally authorized representative (LAR) for participants with cognitive or decisional impairment?**

   ☐ **No**

   ☐ **Yes** *Your application must describe the use of an LAR. If you plan to obtain consent from an experimental subjects' legal representative,* ***the IRB must first determine that the research is intended to be beneficial to the individual experimental subject.*** *Please see the definition of research involving a human being as an experimental subject above.*

6. **Are you requesting a waiver of consent or parental permission?**

   ☐ **No** *Go to question 7.*

   ☐ **Yes**

   a. **If yes, does the research involve interventions or interaction with the subjects?**

      ☐ **No** *If the research participant does not meet the definition of an "research involving a human being as an experimental subject" (see definitions above). You may request a waiver of consent in the ERICA application.*

      ☐ **Yes** *Granting a waiver of consent for "research involving a human being as an experimental subject" is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering ASD(R&E) or a delegated head of DoD component. This waiver must be provided to the IRB and included in the IRB application.*

7. **Are you requesting an exception from informed consent for "emergency medicine research" as defined in FDA regulations (21 CFR 50.24)?**

   ☐ **No**

   ☐ **Yes** *Research Subject to Department of Defense requirements is prohibited from using an exception from consent in emergency medicine research unless a waiver is obtained from the Secretary of Defense.*

8. **Have you verified the disclosure for research-related injury of the DoD component related to your research?**

☐ **No** *If your study involves greater than minimal risk, you must verify what plan to require payment or reimbursement of medical expenses, provision of medical care, or compensation for research-related injuries is required by the DoD component related to your research.*

☐ **Yes** *Disclosure for research-related injury must be included in the consent document for studies involving greater than minimal risk.*

9. Does your research include prisoners (including detainees and prisoners of war)?

☐ **No** *Go to question 10.*

☐ **Yes** *Your study is ineligible for expedited review and will be considered at a convened board meeting with the presence of a prisoner representative. Please ensure your application indicates that prisoners are involved on the Participants page (3).*

a. If yes, does your study involve detainees or prisoners of war?

☐ **No** *Please ensure that your application states that detainees and prisoners of war will not be excluded from the research on the Participants page (3).*

☐ **Yes** ***Research involving detainees or prisoners of war (POW) as a human subject is prohibited.*** *This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition. Your application may only be approved if you have outlined this use in compliance with this exception in your application.*

10. Does your research involve classified information (as defined in Executive Order 13526)?

☐ **No**

☐ **Yes** ***The University of Utah does not conduct or permit its faculty to conduct classified or secret research at the University or under a grant administered by the University.*** *Your application cannot be approved.*

11. Is your research conducted outside of the United States?

☐ **No**

☐ **Yes** *Please attach documentation of local host country IRB approval (or equivalent) on the Documents and Attachments page of the ERICA application.*

12. Have you provided scientific review of the research for the IRB to review?

☐ **No** *Make arrangements with your chair or dean to conduct an ad hoc scientific review and submit the review* ***prior*** *to IRB review of your application. If your study appears is determined*

exempt or determined to be non-human subject research, requesting scientific review from your chair or dean is not necessary.

☐ **Yes** *Please attach scientific review on the Documents and Attachments page of the ERICA application.*

Investigator Assurances:

☐ I must report the following within 30 days to the DoD human research protection officer:

1. When significant changes to the research protocol are approved by the IRB (including changes to key investigators or institutions, decreased benefit or increased risk to participants in greater than minimal risk research, addition of vulnerable populations as participants, addition of DoD-affiliated personnel as participants).
2. The results of the IRB continuing review.
3. Change of reviewing IRB.
4. When the University of Utah is notified by any Federal department, agency, or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol.
5. Any problems involving risks to participants or others, suspension, or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported human participant research.
6. Change in status when the researcher learns a previously enrolled participant becomes pregnant or a participant and the protocol was not reviewed in accordance with the applicable Subpart (B or C).
7. Closure of a DoD-supported study.

☐ I must submit any surveys performed on Department of Defense personnel for review and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

_____ _____

Principal Investigator Name Date

_____

Signature