INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

DEPARTMENT OF DEFENSE SUPPLEMENT

Instructions

A Department of Defense (DoD) Component is the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities and all other organizational entities in the Department of Defense.

Research conducted or supported by a DoD Component requires additional information to be submitted to the IRB with the research application. Investigators should complete and attach this document to the Documents and Attachments page of the ERICA application.

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). Therefore, the investigator should retain this document for reference.

IRB Number:

PI:

Study Title:

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 U.S. military personnel as participants in research?
   ☐ No. *Go to question 4.*
   ☐ Yes.
   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 ombudsman 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. *If your study involves greater than minimal risk, the IRB will appoint the independent ombudsman as described above. If your study involves minimal risk, The IRB will determine whether an ombudsman should be appointed. The decision to require the appointment of an ombudsman 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.
   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 from an experimental subjects' legal representative? Please see the definition of research involving a human being as an experimental subject on the IRB Glossary on the IRB website).

   - ☐ No.

   - ☐ Yes. *In order 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.*

6. Are you requesting a waiver of consent for "research involving a human being as an experimental subject" (see definition in the IRB Glossary on the IRB website)? . *If the research participant does not meet the definition of an "experimental subject", you may request a waiver of consent in the ERICA application.*

   - ☐ No.

   - ☐ 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 plant 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?

☐ No.

☐ Yes. *Your study is ineligible for expedited review and will be considered at a convened board meeting with the presence of a prisoner representative.*
If yes, does your study comply with the following prohibitions?

- Research involving a detainee as a human participant 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.
- Research involving prisoners of War is prohibited.

☐ No. *Your application will not be approved until you have complied with the required guidelines (above) for research involving prisoners.*

☐ Yes.

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

☐ No.

☐ Yes. *All Department of Defense conducted or supported non-exempt human subject research involving classified information additional requires Secretary of Defense approval. Approval must be submitted to the IRB. Additional requirements must be followed according to the Department of Defense Instruction 3216.02 13.*

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.*

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.
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.

☐ 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