1. PURPOSE

1.1. Research supported by the Department of Defense (DoD) must be reviewed by the IRB under an additional set of federal regulations (32 CFR 219) and requires compliance with additional Directives, and Instructions.

1.2. Responsibility for adhering to DoD requirements for human subjects research is shared between the researchers and their team, the University administration, and the DoD.

1.3. This document describes requirements and recommendations for researchers to use when planning and developing research involving the DoD.

2. DEFINITIONS

2.1. *Minimal risk* means, that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (32 CFR 219.102(i)).

2.1.1. When making minimal risk determination, the inherent risks certain categories of participants face in their everyday lives should not be considered. When research involves a special population, the risks imposed by the research must not be evaluated against:

- The inherent risks encountered in the populations' work environment (e.g., emergency responder, pilot, soldier in a combat zone); or
- The inherent risks of having a medical condition (e.g., frequent medical tests or constant pain).

2.2. *Greater than minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater. Studies that fall under this category will range in their probability of a moderate to severe event occurring as a result of study participation (and the level of safety monitoring will depend on that probability) but there are adequate surveillance and protections in place to identify adverse events promptly and to minimize harm.

2.3. *Research involving a human being as an experimental subject*, means 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 interventions or interaction. (DODI 3216.02, Enclosure 2.Definitions).

2.4. *Research monitor*, means an individual with expertise consonant with the nature of risk(s) identified within the research protocol, whose role is to protect the safety and well-being of human subjects (DODI 3216.02, Enclosure 2.Definitions).

3. SCOPE and APPLICABILITY

3.1. This information applies to all non-exempt human subjects research involving the DoD. For exempt research see section 5.5 below.

3.2. Research involves the DoD when any of the following apply:

- The research is funded by a component of the DoD (e.g., Navy, Army, Air Force)
- The research involves cooperation, collaboration, or other type of agreement with a component of DoD

- The research uses property, facilities, or assets of a component of DoD
- The subject population will intentionally include personnel (military or civilian) from a component of DoD
- **Note: DoD policies and requirements do not apply when DoD personnel incidentally participate as subjects in research that is not supported by DoD, and DoD personnel are not an intended population of the research.**

3.3. The Department of Defense components include, but may not be limited to:

- Department of Defense
- Navy
- Office of Naval Research
- Naval Academy
- U.S. Naval Observatory
- Army
- U.S. Army Corps of Engineers
- Military Academy (e.g., West Point)
- Air Force
- Air Force Academy
- Marines
- Coast Guard
- Coast Guard Academy
- National Guard
- Missile Defense Agency
- Defense Advanced Research Projects Agency (DARPA)
- Pentagon Force Protection Agency
- Defense Intelligence Agency
- National Geospatial-Intelligence Agency
- National Security Agency
- National War College
- Other DoD facilities

4. INVESTIGATOR RESPONSIBILITIES

Investigators have the following responsibilities when conducting activities that involve the DoD:

4.1. **Planning:** DoD-related research activities typically involve additional compliance requirements before investigators may begin their research. Investigators should anticipate and plan accordingly, which may require coordinating between the DoD, research team, and IRB. Investigators are encouraged to plan ahead in order to ensure that human subjects activities can begin in a timely manner.

4.2. **DoD Funding:** Investigators are not allowed to expend DoD funds for any research involving human subjects until all the following requirements have been met:

- The IRB has reviewed and approved the research (or determined the project was exempt or non-human subjects research);
- All materials (approved protocol, approval notice, consent forms, etc.) have been provided to the DoD funding agency; and

- The DoD has completed an administrative review of the research activities and the Human Research Protections Program Officer (HRPPO) has given final approval of the human subjects research.

4.3. **DoD Approval of Surveys and Interviews:** Research involving the administration of surveys to, or interviews of, DoD personnel (military or civilian) may require DoD approval of the surveys or interview questions.

4.4. **Waiver of Consent:** The requirement to obtain consent cannot be waived for any research involving the DoD, and where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction, except under one of the following conditions:

- The research is intended to be beneficial to the subject, the subject lacks the capacity to provide consent, and a legally-authorized representative will provide consent. For example, research involving a waiver of consent for cognitively impaired individuals may be approved, so long as it meets the criteria for approving such a waiver.
- The Head of the DoD component involved in the research may waive the requirement for consent with respect to a specific project, in order to advance the development of a medical product necessary to the Armed Forces, but only if the research may directly benefit the subject and the research is carried out in accord with all other applicable laws and regulations.
- This prohibition does not apply to pre-screening or screening of records to identify potential participants. The IRB may grant a waiver of consent for these types of activities.

4.5. **Legally-Authorized Representatives:** Informed consent may be provided by a legally-authorized representative of subjects if: 1) the subject lacks capacity due to age, condition, or other reason, to make a decision regarding consent to participate in the research; AND 2) the IRB has determined that the research is intended to be beneficial to the individual subjects.

4.6. **Research Monitor:** A research monitor (see above definition in section 2.4) is required for any research that is determined to be greater-than-minimal risk to the subjects.

4.6.1. The IRB is responsible for determining whether proposed research activities are no more than minimal risk or greater than minimal risk. The IRB may re-review research activities to reassess the risk level determination made to ensure adequate protections are in place to protect the subjects from risk or harm.

4.6.2. Depending on the type of research, a medical monitor may be appropriate for bio-medical research activities, whereas a non-medical monitor may be appropriate for social-behavioral research activities.

4.6.3. The IRB may require a research monitor for a portion of, and for all, aspects of studies involving greater than minimal risk.

4.6.4. The IRB must approve a written summary from the Principal Investigator regarding the monitor's duties, authorities, and responsibilities.

- The research monitor must be appointed by name;
- Principal Investigators must name the research monitor in the protocol application;

- The monitor may be an ombudsperson or a member of a data safety monitoring board;
- The research monitor must be independent of the research team conducting the research;
- There may be more than one monitor if different skills or experiences are needed.

4.6.5. The duties of the research monitor are determined on the basis of specific risks or concerns about the research and may include the following:

- Observing recruitment, enrollment and consent processes;
- Overseeing the study interventions and/or interactions;
- Reviewing monitoring plans and unanticipated problems involving risks to participants or others;
- Overseeing data collection and analysis;
- Discussing the research protocol with investigators;
- Interviewing human research participants;
- Consulting with others outside of the study; and
- Reporting observations and finding to the IRB or a designated official.

4.7. **Additional Protections:** If research involves children, prisoners, pregnant women or neonates or fetuses, or military personnel, then additional protections apply.

4.7.1. Research involving pregnant women, neonates, or fetuses – Additional protections of 45 CFR 46 subpart B apply (see UCSB HSC SOP No 25 for requirements).

4.7.2. Research involving prisoners – Additional protections of 45 CFR 46 subpart C apply (see UCSB HSC SOP No 27 for requirements). Research involving detainees as defined in the DoD Directive 2310.01E is prohibited.

4.7.3. Research involving children – Additional protections of 45 CFR 46 subpart D apply (see UCSB HSC SOP No 26 for requirements).

4.7.4. Research involving military personnel – Additional protections for military personnel being recruited for research activities involving greater-than-minimal risk studies apply:

- Officers are not permitted to influence the decision of their subordinates on whether or not to participate in the research;
- Officers and senior non-commissioned officers have a separate opportunity participate in the research;
- Officers and senior non-commissioned officers may not be present at the time of recruitment for the research;
- During recruitment briefings to a unit where a part of the unit is being recruited to participate in the research, an independent ombudsman is present
- Limitations on dual compensation prohibit an individual from receiving payment from more than one position for more than 40 hours of work in one calendar week, which includes temporary, part-time, and intermittent appointments.

4.8. **Scientific Merit Review:** The Army and Navy require independent scientific review and approval prior to IRB review of new applications and substantive modifications.. This requirement may not apply to other components of the DoD. Investigators are encouraged to check with their Program Officer for DoD-specific requirements.

4.8.1. Documentation of scientific merit review is the responsibility of the investigator. A copy of the completed scientific merit review must be submitted to the IRB prior to IRB review and approval of research activities.

4.8.1.1. The scientific merit review must include the names of the reviewers and the date(s) of review.

4.8.2. An independent scientific merit review may be conducted by the funding agency, by an established internal review mechanism, or by an individual within the investigator's school or department, such as a Chair or Dean not associated with the research, but who is knowledgeable about the research.

Note: The IRB cannot conduct a scientific merit review for investigators.

4.8.3. The scientific merit review should include consideration of the following topics:

- Significance of the research – Does the research address a problem of scientific and/or practical importance? Is there a specific hypothesis being tested?
- Approach of the research – Are the conceptual framework, design, methods, and analyses adequately developed, feasible and well-integrated and appropriate to the aims of the study?
- Research team- Are the researchers appropriately trained and have expertise in the scope of the work?
- Risk/benefit analysis – Are the risks and potential discomforts identified and are the risks reasonable in relation to the potential benefits? Have study endpoints and criteria for early withdrawal from the study been identified?
- Sample size – Is the sample size appropriate enough to yield statistically significant results?

4.9. **Education and Training Requirements:** The DoD education and training requirements exceed the training requirements of UCSB.

4.9.1. Initial training – DoD requires "all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects must complete initial and ongoing research ethics and human subjects protections training appropriate to each individuals level of involvement, duties, and responsibilities" (Secretary of Navy SecNav Instruction 3900.39D)

4.9.2. Continuing education – DoD requires continuing education every three years.

4.9.3. In order to fulfill these training requirements, investigators should complete the applicable CITI Program training module(s).

4.10. **International Research:** Research involving an international component may have additional requirements. DoD research activities that involve subjects who are not U.S. citizens or Department of Defense personnel must provide the following documentation to the IRB:

- Permission from the host country (as applicable);

- Ethics review and approval by the host country or by a local Naval IRB with host country representation;
  Note: Additional safeguards might not be applicable to social-behavioral research involving no more than minimal risk.

4.11. **Collaborations:** When investigators collaborate on DoD-related research activities, additional requirements may apply.

4.11.1. Investigators should notify the IRB of any collaborative arrangements with other institutions or individuals that are not at UCSB. Investigators are encouraged to contact the IRB to determine engagement of institutions or individuals and whether any institutional authorization agreements need to be initiated between collaborators.

4.11.2. Collaborating institutions must hold a Federal Wide Assurance in order to conduct human subjects research activities that involve the DoD.

4.12. **Documentation:** Investigators must adhere to DoD requirements for maintaining research-related and compliance-related records in their files. Investigators are encouraged to contact their Program Officer to determine which requirements are applicable to their research activities.
Note: It is the investigator's responsibility to provide the DoD with all documents that are required by the DoD.

4.13. **IRB Application:** Investigators should include with their IRB application the following information:

- Documentation of scientific merit review (see above section 4.8)
- If data is to be shared with other investigators, this must be described in the Procedures section of the protocol and in the consent forms. A description of how data will be protected should also be included in the Risks section of the protocol.
- The consent forms should include a statement that the study is funded by the DoD (if applicable) and DoD representatives may access research records for the protection of human subjects.

4.14. **Post-approval requirements:** Investigators must adhere to DoD requirements post-IRB approval. This includes the following responsibilities:

- Continuing education;
- Furnish the DoD with publications, presentations and reporting results from the research activities. This information should also be provided to the IRB during continuing review;
- Continuing review by the IRB of research activities no less than annually. Continuing review may be more frequent, but no less than once per year as determined by the IRB;
- Modifications approved by the IRB must also be submitted for review by the HRPPO before initiation.
- Submit reports of any audits, investigations, inspections, or non-compliance to the IRB and the DoD.

5. IRB RESPONSIBILITIES

The IRB has the following responsibilities when investigators conduct activities that involve the DoD:

5.1. **Information:** The IRB staff are responsible for providing investigators with advice and guidance on the IRB review process for DoD-related research activities.

5.2. **Identification:** The IRB staff are responsible for ensuring the IRB reviews human subjects research involving the DoD in accordance with DoD policies.

5.3. **Collaborations:** The IRB staff will establish and document collaborative agreements with other institutions or non-UCSB individuals engaged in DoD-related research.

5.4. **Review responsibilities:** The IRB is responsible for initial, modification, and continuing review of human subjects research activities in accordance with DoD regulations and UCSB policies and procedures.

5.4.1. ***Initial Review:***

5.4.1.1. In addition to following DoD regulations, the IRB will follow the procedures for review as described in UCSB HSC SOP No 14 for initial review.

5.4.1.2. The IRB must assess the level of research risks to the subjects and document if the research involves no-greater-than-minimal risks to the subjects. The risk level determination is documented in the IRB meeting results for each study.

5.4.1.3. If the research is determined to be greater-than-minimal risk to the subjects, then the IRB must assess the appropriateness of an appointed research monitor with regard to: type of monitor, qualifications, and roles and responsibilities of the monitor.

5.4.1.4. The IRB must conduct a risk/benefit analysis of the human subjects research activities.

5.4.2. ***Modification Review:***

5.4.2.1. In addition to following DoD regulations, the IRB will follow the procedures for review as described in UCSB HSC SOP No 18 for amendments.

5.4.2.2. For research that is already DoD-related, the criteria for level of IRB review (i.e., expedited versus full board) are the same for DoD-related research.

5.4.2.3. For substantive changes, the IRB staff will have the investigator confirm whether the DoD-related research activities require re-evaluation of the scientific merit prior to setting up the modification for review.

5.4.2.4. For research that was previously not DoD-related, but now becomes DoD-related because of the modification, the IRB will apply DoD regulations to the request for modification.

5.4.2.5. If the project was previously reviewed by full board and was not previously DoD-related, then the amendment must also be reviewed by full board because a new set of regulations are applicable.

5.4.3. ***Continuing Review:***

5.4.3.1. In addition to following DoD regulations, the IRB will follow the procedures for review as described in UCSB HSC SOP No 17 for continuing review.

5.4.3.2. IRB staff conduct an administrative review to ensure the following two DoD requirements have been met:
Continuing education: The requirement for continuing education has been met.
Research results: Any research results (i.e., publications, presentations, and/or reporting resulting from the research) will be provided to the IRB for continuing review.

5.5. When the IRB determines that an activity is either not research involving human subjects or is exempt research involving human subjects the HRPPO must concur with the IRB's determination before activities can begin.

5.6. The Office of Research is required to report to the DoD any of the following events or situations that occur for DoD-related research involving human subjects:

- Serious or continuing non-compliance;
- Suspension or termination of research;
- Unanticipated problems or adverse events involving risks to the subjects;
- Significant communication between institutions conducting research and other federal departments and agencies, regarding compliance and oversight.
- When a specific situation involves reporting to more than one federal agency, then the letter should be addressed to the primary agency and a copy is sent to the DoD.

References and Citations:

32 CFR 219, "Protections of Human Subjects"
45 CFR 46, "Protections of Human Subjects" Subparts B, C, D
48 CFR 235, "Research and Development Contracting" Defense Federal Acquisition Regulations
Title 10, United States Code, Section 980 "Limitation on use of humans as experimental subjects"
Title 18, United States Code 48 CFR 207 "Acquisition Planning", Section 209
Army Regulation 70-25 "Use of Volunteers as Subjects of Research"
Department of Defense (DoD) Directive 3216.2 "Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research"
DoD Directive 2310.01E "DoD Detainee Program"
DoD Directive 5500.7-R, Joint Ethics Regulation, "Standards of Conduct"
DoD Instruction 1100.13 "DoD Surveys"
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research"
Naval Operations, OPNAV INSTRUCTION 5300.8C Army Human Research Protections Office Institutional Policies and Procedures "Coordination and Control of Personnel Surveys"
Secretary of the Navy, SCNAV INSTRUCTION 3900.39D, "Human Research Protection Program"
Secretary of Defense Memorandum, HA Policy 05-003, "Policy for Protection of Human Subjects in Department of Defense Sponsored Research"

Supplement (DFARS). Specifically: 48 CFR 235.072 48 CFR 252 "Solicitation Provisions and Contract Clauses", part of Defense Federal Acquisition Regulations Supplement (DFARS). Specially: 48 CFR 252.235-7004

*Based on guidance materials created by the University of California, San Francisco Human Research Protections Program "Guide to Department of Defense Research"