Department of Defense (DoD) Research

Background

Human research sponsored or funded by the Department of Defense (DoD) must be reviewed by the IRB under an additional set of federal regulations (32 CFR 219) and comply with DoD Instruction 3216.02. The DoD Directive 3216.02 contains additional requirements for compliance activities, documentation, and research participant protections that must be met. DoD requirements specific to the separate DoD components, such as Army, Navy, Air Force and Marine Corps, may also apply (see *Resources* at the end of this guidance).

What Qualifies as DoD Research?

Research is considered to involve the DoD when:

- **Funding:** The research is funded by a component of DoD. Example: A grant from the Office of Naval Research.
- **Collaboration:** The research involves cooperation, collaboration, or another type of agreement with a component of DoD. Example: An Army Medical Laboratory will conduct malaria antigen detection tests for study.
- **Facilities:** The research uses property, facilities, or assets of a component of DoD.
- **Personnel:** The subject population will intentionally include personnel (military and/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.

Considerations for DoD Research:

1. When appropriate, research protocols must be reviewed and approved by the IRB prior to DoD approval. Consult with the DoD funding component to see if this is a requirement.
2. DoD Components may have additional requirements beyond those outlined in the Office for Human Research Protections Federalwide Assurance or when human research is conducted in a foreign country. The Component will communicate the unique requirements by providing the principal investigator (PI) with an early communication applicable to the proposed research. The PI must provide the IRB with any specific unique requirements outlined in DoD Component communication at time of the study's submission. The PI must submit documentation of IRB review and approval to the DoD Component to confirm the protocol is compliant with federal and DoD requirements and to concur with the IRB's determinations.
3. DoD component-level administrative review (CLAR) must be conducted when:
    - Human research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are U.S. citizens.
    - The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b).
    - Large scale genomic data (LSGD) is collected from DoD-affiliated personnel. LSGD includes data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. (See definition in DoD Instruction 3216.02, *G.2 Definitions*)
    - The research is required to be approved by the DoD Office for Human Research Protections (DOHRP) in addition to the Component Office of Human Research Protections (COHRP) in accordance with DoD Instruction 3216.02.

4. For projects that are funded or regulated by the DoD, the PI will complete the *Appendix for DoD Research* and include it in their submission in eIRB. All human research conducted or funded by the DoD must meet the standards outlined in the *Appendix for DoD Research.*
5. DoD Components might have stricter requirements for research-related injury than the Department of Health and Human Services (DHHS) regulations.
6. The University of Arizona does not conduct classified DoD research.
7. The University of Arizona does not allow research involving chemical or biological agents, including research for prophylactic, protective, or other peaceful purposes involving chemical or biological agents.

DoD Reporting Requirements

As required by DoD Instruction 3216.02, for DoD-supported research, the following must be promptly reported to the COHRP:

- 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.
- Change of reviewing IRB.
- When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of a human research protection program is under investigation for cause involving a DoD-supported research protocol.
- 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.
- The results of the IRB's continuing review, if required.
- Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.
- Closure of a DoD-supported study
- Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.
  - For DoD-conducted research, the human protections director must notify the COHRP.
  - For DoD-supported research, the non-DoD organization must notify the DOHRPO and other federal agencies.
  - The DOHRP must concur with the IRB before the participant can continue to participate while a prisoner.

DoD Requirements for Ethics Training

- Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human research participant's research.
- The University's training meets the basic requirements of the DoD required training. Copies of training requirements must be provided upon request to the HSPP or the DoD.
- The DoD may evaluate the education policies to ensure the personnel are qualified to perform research, based on the complexity and risk of the research.

- The DoD may require additional training be taken for the IRB Chair, staff, and members; and researchers and research staff. If such requests are made, the HSPP will notify the correct individuals.

Requirements for Non-DoD Institutional Review:

- The IRB must consider the scientific merit of the research.
- The IRB may rely on outside experts to provide an evaluation of the scientific merit.
- Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD Components, additional review is required.
- The IRB must determine that the disclosure includes that provisions for research-related injury follow the requirements of the DoD component.

DoD Requirements for Recruitment

- Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
- Military and civilian supervisors, officers, and others in the chain of command must not be present at any research participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable.
- For research involving recruitment of DoD-affiliated personnel in research determined greater than minimal risk, as defined by 32 CFR 219, and when recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:
  - Must not have a conflict of interest with the research or be a part of the research team.
  - Must be present during the recruitment process, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials.
  - Should be available to address DoD-affiliated personnel's concerns about participation.

DoD Requirements for Informed Consent

If the research participant meets the definition of "experimental subject," the following must be considered:

- If consent is to be obtained from the legal representative of the experimental subjects as defined in DoD Instruction 3216.02, the research must intend to benefit each participant enrolled in the study.
- A waiver of the consent process is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering. If the subject is not an experimental subject, the IRB is allowed to waive the consent process. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:
  - The research is necessary to advance the development of a medical product for the Military Services.
  - The research might directly benefit the individual experimental subject.
  - The research is conducted in compliance with all other applicable laws and regulations.
- An exception from consent in emergency medicine research is prohibited unless the Secretary of Defense approves a waiver of the advance informed consent provision of 10 USC 980. The PI is responsible for ensuring that this waiver has been obtained by the DOHRP and providing such documentation to the IRB upon review of the submission.

For research involving DoD-affiliated personnel, the consent documentation must include, if applicable, potential risks for revocation of clearance, credentials, or other privileged access or duty.

DoD Requirements for Compensation in Research

- U.S. military personnel are prohibited from receiving pay of compensation for research during duty hours but may be compensated when participation occurs when personnel are involved in the research when not on duty.
- Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood draw.
- Non-federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
- DoD employees (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments.

DoD Requirements for Special or Vulnerable Populations

Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D.

The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

<u>Research Involving Pregnant Women, Human Fetuses and Neonates</u>

- 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 women 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.
- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
- Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:
  - May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
  - Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
- The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.
- For human participant research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHPR prior to research starting.

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Research Involving Prisoners

In addition to the categories of permissible human participant research involving prisoners identified in DHHS regulations Subpart C, additional categories are permissible:

- Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted but must first be approved by an IRB and meet the requirements of Subpart C and DoD Instruction 3216.02.
- In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
  - The research describes the prevalence or incidence of a disease by identifying all cases, or studies potential risk factor association for a disease.
  - The research presents no more than minimal risk.
  - The research presents no more than an inconvenience to the participant.

Research Involving Detainees

- 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 U.S. military personnel in the same location for the same condition.

Research Involving DoD-Affiliated Personnel

Service members and DoD-affiliated personnel are considered to be vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization. Therefore, additional protections for DoD-affiliated personnel are required, as follows (DoD Instruction 3216.02 section 3.9 (f)):

- If the research involves DoD-affiliated personnel as participants and if the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.
- If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research.
- Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research.
- Service members and all Reserve component and National Guard members in a federal duty status are considered to be adults. If a Service member, Reserve component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the recruitment process and the necessity of including such member as a human participant.
- Research involving LSGD from DoD-affiliated personal is subject to additional requirements:
  - The disclosure of DoD-affiliated personnel's genomic data may pose a risk to national security; accordingly, written materials must describe administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.
  - All research involving LSGD collected from DoD-affiliated personnel must have a certificate of confidentiality from DHHS (Title 42, USC, and Public Law 114-255).
  - Research involving LSGD collected from DoD-affiliated personnel is subject to DoD component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens.

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Resources

- DoD Protection of Human Research Subjects: DoD Instruction 3216.02
- DoD Human Subjects Protection Regulations: 32 CFR 219
- DoD Limitation on use of humans as experimental subjects: 10 USC 980
- Department of Navy Human Research Protections Policies:
  - SECNAVINST 3900.39D
  - OPNAVINST 5300.8C
- U.S. Army Regulation on "Use of Volunteers as Research Subjects": 70-25
- U.S. Air Force Protection of Human Subjects: USAF Instruction 40-402
- U.S. Marine Corps Policy: MCO 3900.18