1. **Introduction**

Research supported by the Department of Defense (DoD) involving human subjects is subject to the Federal Policy for the Protection of Human Subjects in Research, i.e., the “Common Rule.” However, because of potential risks that are unique to DoD employees (e.g., research affecting a service member’s ability to deploy), DoD Instruction 3216.02 lays out additional requirements. These requirements include special protections for research participants and additional review and reporting requirements. Investigators should review these requirements when planning a DoD-supported research project as they may add a significant amount of time to the review and approval process.

Each DoD Component may have additional requirements beyond those included in this Guidance. Principal investigators (PIs) are advised to check with their sponsoring DoD Component program manager about any additional requirements.

2. **When is Human Research Subject to DoD Special Requirements?**

Human research must comply with DoD requirements when:

- The research is funded by a DoD Component, including cases where S&T is the recipient of a sub-award from the direct recipient of DoD funds; or
- The research involves cooperation, collaboration, or other type of agreement with a DoD Component; or
- The research uses property, facilities, or assets of a DoD Component; or
- The subject population will intentionally include personnel (military and/or civilian) from a DoD Component. (DoD requirements do not apply when DoD personnel incidentally participate as research subjects, where they are not the intended research population or where the project is not DoD-supported).


The HRPO for the sponsoring Component must perform an administrative review of the research before activities with human subjects research can begin. This administrative review takes place after:

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1 Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (November 8, 2011), hereinafter “DoDI 3216.02.”
2 DoDI 3216.02, encl. 3, p.35, definition of “DoD-supported research involving human subjects.”
3 DoDI 3216.02, encl. 3, ¶ (4) (c).
• completion of S&T IRB review and approval; or
• IRB determination that the research is exempt or does not involve human subjects.

The review involves confirmation that S&T and the proposed research comply with DoD requirements for the protection of human subjects. While the HRPO review is not an IRB review, the HRPO may require changes to the research prior to the start of the research. The PI is responsible for submitting the information required by the sponsoring Component.4

**OSPA will not issue a MoCode until it has receiving the following notifications:**

1. IRB approval, or an IRB determination that the research is exempt or does not involve human subjects; and
2. HRPO administrative review.

4 For research supported by the Army Research Laboratory (ARL), see [https://www.arl.army.mil/www/default.cfm?page=3405](https://www.arl.army.mil/www/default.cfm?page=3405) for additional information and links to the HRPO forms, including the HRPO Review Submission form to be submitted by the PI to the HRPO.

4. **Special requirements for IRB Review of DoD Research**

**A. Education and Training Requirements**5

The DoD requires that all individuals involved in the “design, conduct, or approval of human research involving human subjects” receive initial and continuing education on human subjects research. CITI’s Research Investigator training (Biomedical or Social and Behavioral, respectively), renewable every three years, meets the training requirements for many DoD Components. Investigators are responsible for ensuring that all study team members engage in the mandatory CITI training. Instructions for accessing the training are located at [https://irb.mst.edu/citi-program-training/](https://irb.mst.edu/citi-program-training/). The DoD Component may evaluate S&T’s training program to ensure that personnel are qualified to perform the research, based upon the complexity and risk of the research.

**B. Scientific Review**6

Research involving DoD Components requires documentation of scientific review prior to IRB approval of new applications and substantive amendments.

The PI is responsible for obtaining scientific review of the proposal from his/her Department Chair or designee. The Department Chair/designee is responsible for determining whether the proposed research has scientific merit, pursuant to the criteria outlined in 32 C.F.R. §219.111. Upon completion of the review, the Department Chair/designee shall provide the PI with a signed document stating that the proposed research meets the scientific merit requirements of 32 C.F.R. §219.111. The PI will include this documentation with his/her IRB application.

5 DoDI 3216.02, encl. 3, ¶ 5.
6 DoDI 3216.02, encl. 3, ¶ 4.

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4 For research supported by the Army Research Laboratory (ARL), see [https://www.arl.army.mil/www/default.cfm?page=3405](https://www.arl.army.mil/www/default.cfm?page=3405) for additional information and links to the HRPO forms, including the HRPO Review Submission form to be submitted by the PI to the HRPO.
C. DoD Approval of Surveys/Interviews

Research involving surveys or interviews with DoD personnel (military or civilian) or their families typically require DoD approval. The DoD Component program manager can confirm any additional review requirements and the timing of the review (before or after IRB review). Documentation of this review must be provided to the IRB.

D. International Research

If the research will be conducted outside of the United States, the PI must furnish to the IRB information regarding the relevant laws and requirements of the host country as well as the cultural context of the research. The PI is responsible for determining whether the sponsoring DoD Component requires an additional ethics review by the host country or a local IRB with host country representation.

E. Collaboration with Other Institutions

A PI developing a proposal for DoD funding or other support involving other collaborating institutions must consult the sponsoring DoD Component and IRB staff early in the proposal development process to identify additional requirements for multi-site research.

For collaborative research involving S&T and DoD researchers, S&T may choose to rely upon the DoD IRB of for review and oversight. For collaborative research involving S&T and non-DoD institutions, S&T and the collaborating institutions must sign an IRB authorization agreement, which includes a statement of work specifying the roles and responsibilities of the relied-upon IRB.

In order to ensure the consistent protection of subjects pursuant to DoD requirements, a PI conducting DoD-sponsored multi-site research must submit information to the IRB on the Federalwide Assurances (FWAs) held by collaborating institutions.

5. Unique Human Subject Protections Required for DoD-related Research

A. Prohibited Research

Research with detainees (prisoners of war) is prohibited. The definition of “prisoner of war” may vary by DoD Component. Under no circumstances shall the IRB approve research involving prisoners of war, as defined by the specific DoD Component supporting the research.

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7 DoDI 3216.02, encl. 3, p. 36, definitions of “research involving a human being as an experimental subject” and “intervention and interaction.”
8 DoDI 3216.02, encl. 3, ¶ 4(c)(2).
9 DoDI 3216.02, encl. 3, ¶ (7)(c).
B. DoD Limitations on Waivers of Informed Consent

If a research subject meets the definition of “experimental subject,” DoD prohibits a waiver of consent unless the PI obtains a waiver from the Assistant Secretary of Defense for Research and Engineering. The IRB shall not approve waiver of consent for research on “experimental subjects” unless the Assistant Secretary of Defense has issued a waiver.

The Assistant Secretary of Defense for Research and Engineering may waive this consent requirement for a specific project if: (a) the research is necessary to advance the development of a medical product necessary to the Armed Forces; (b) the research may directly benefit the subject; and (c) the research is carried out in accordance with other applicable laws and regulations.

C. Definition of Minimal Risk

DoDI 3216.02 cautions that the Common Rule definition of minimal risk that includes the phrase “ordinarily encountered in daily life or during the performance of routine physical or psychological tests” must not be interpreted to include the inherent risks that certain individuals face in their everyday lives, such as a soldier in a combat zone or an individual with a particular medical condition.

D. Research Monitor Required for More than Minimal Risk Research

A research monitor must be appointed for all research that involves more than minimal risk. The monitor must be independent of the research team and possess sufficient expertise to evaluate the risks and conduct of the research.

The PI must identify a research monitor by name and have the selection approved by the IRB. The IRB may also choose to appoint more than one research monitor (e.g., if different skills or experiences are necessary). The PI must furnish a written summary of the monitor’s duties, authorities, and responsibilities, for IRB approval.

E. Vulnerable Populations

The DoD requires that the protection of Common Rule subpart B (Pregnant Women/Fetuses), C (Prisoners), and D (Children) be applied to the research it supports.

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10 DoDI 3216.02, encl. 3, ¶ 9; 10 U.S.C. § 980.
12 DoDI 3216.02, encl. 3, ¶ 6(b).
13 DoDI 3216.02, encl. 3, ¶ 8.
14 See DoDI 3216.02, encl. 3, ¶ 8, for a description of the research monitor’s duties.
15 DoDI 3216.02, encl. 3, ¶ 7.
16 See DoDI 3216.02, encl. 3, ¶ 7, for a description of additional DoD considerations for these populations.
F. Provisions for Research-related Injury

The PI is responsible for informing IRB staff of the DoD Component’s requirements for the provision of care in the case of a research-related injury.

If the DoD Component has stricter requirements than the Common Rule, the PI, with assistance from the IRB staff, must obtain prior permission from the Institutional Official or designee. If the Institutional Official approves, the PI will document the approval and include the appropriate provisions in the informed consent form. The IRB must approve the informed consent disclosure.

6. DoD Personnel as Research Subjects

A. Military Participants

1) Command approval

Command approval may be required for military personnel to participate in human subjects research, as some types of research could impact a soldier’s ability to perform his/her duties. PIs may be asked to provide documentation of Command approval as part of the IRB review.

2) Protection of Service Members from Undue Influence

Officers and senior non-commissioned officers may not influence the decisions of their subordinates regarding participation in DoD-supported research. Superiors of service members shall not be present at any recruitment sessions or during the consent process. The PI must recruit superior officers in a separate session from subordinates.

3) Ombudsman

Greater than minimal risk: for studies determined to be more than minimal risk and where recruitment occurs in a group setting, an ombudsman must be present to ensure that information is clearly, accurately, and adequately presented and that the voluntary nature of participation is emphasized. The ombudsman may be also be the research monitor.

Minimal risk: for research determined to be no greater than minimal risk and where recruitment occurs in a group setting, the IRB shall determine when it is appropriate to appoint an ombudsman.

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17 DoDI 3216.02, encl. 3, ¶ 10.
18 DoDI 3216.02, encl. 3, ¶ 7(e)(1)(a).
19 DoDI 3216.02, encl. 3, ¶ 7(e)(1)(b) and (c).
20 DoDI 3216.02, encl. 3, ¶ 7(e)(1)(d).
B) DoD Civilian Personnel

DoD civilian personnel are afforded the same protections as military personnel. The requirement for an ombudsman is at the discretion of the IRB.

C) Compensation Limits

1. On-duty federal personnel, including military personnel:
   a. Compensation is not allowed for general research participation.
   b. May be compensated up to $50 for blood draws if the research meets the purposes of 24 U.S.C. §30.

2. Off-duty federal personnel, including military personnel:
   a. Compensation is allowed for general research participation if approved by the IRB; however, payment may not come directly from a federal source. (Payment from a federal contractor or non-federal source is permissible).
   b. May be compensated up to $50 for blood draws if the research meets the purposes of 24 U.S.C. §30.

3. Non-federal personnel:
   a. Compensation is permissible for participation in DoD-supported research in a reasonable amount, as approved by the IRB. Payment may come directly from a federal or non-federal source.
   b. May be compensated up to $50 for each blood draw if the research meets the purposes of 24 U.S.C. §30.

7. Other DoD-Specific Requirements

A. Record-keeping

The DoD requires all institutions engaged in DoD-supported research involving human subjects to retain records for at least three years after research completion. The DoD Component may rely on S&T to keep the required records, or may require that S&T transfer the research records to the DoD Component. Other Federal regulations may apply to the human research and impose longer record-keeping requirements.

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21 DoDI 3216.02, encl. 3, ¶ 7(e)(2).
22 DoDI 3216.02, encl. 3, ¶ 11.
23 DoDI 3216.02, encl. 3, ¶ 15.
B. Reporting Requirements

The following must be reported promptly to the HRPO within 30 days of the event:

- IRB approval of significant changes to the research protocol;
- Results of IRB continuing review;
- Changes to the reviewing IRB;
- Investigations by any Federal department or agency involving a DoD-supported research protocol;
- Study suspensions and terminations;
- Determinations of serious or continuing non-compliance regarding DoD-supported research involving human subjects.

References

**DoD**

- 32 C.F.R. Part 219, Protection of Human Subjects
- 10 U.S.C. § 980, Limitations on the Use of Humans as Experimental Subjects
- 24 U.S.C. § 30, Payments to Donors of Blood for Persons Undergoing Treatment at Government Expense
- DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
- 45 C.F.R. 46, Subparts B, C, D, F

**Department of the Army**

- AR 70-25: Use of Volunteers as Subjects of Research
- AR 40-7: Use of Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule I Controlled Substances

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24 DoDI 3216.02, encl. 3, ¶ 4(b)