

Guidance: Additional Requirements for Department of Defense (DoD) Research April 2015

1. Introduction

Research sponsored by the Department of Defense (DoD) involving collaboration with DoD, or involving DoD facilities or personnel (military or civilian), is subject to additional special requirements to enhance the protection of human subjects. These requirements include special protections for research participants as well as additional review and reporting requirements for the investigator and IRBs. Investigators must be aware of these special requirements when planning a research project as they may add a significant amount of time to the human subjects review and approval process throughout the research.

The focus of this guidance document is on the general requirements outlined in DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, November 8, 2011, and in Navy guidance SECNAV Instruction 3900.39D, Human Research Protection Program, November 6, 2006.

Each DoD Component may have additional requirements beyond those included in this guidance document. PIs are advised to check with their program manager with the sponsoring Component about any additional requirements.

2. What is Department of Defense Research?

Research is considered to involve the Department of Defense when:

- The research is funded by a DoD Component (Attachment A), including cases where U-M is the recipient of a subaward 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).

3. Required DoD Human Research Protections Office (HRPO) Administrative Review

Upon completion of U-M IRB review and approval, including determination of exempt or not IRB-regulated status, the HRPO for the sponsoring component must perform an administrative review of the research before activities with human subjects may begin. The review involves confirmation that the University and the proposed research are in compliance 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 Principal Investigator is responsible for submitting the information required by the sponsoring Component.

4. Special Requirements for IRB Review of DoD Research

4.1 Training Requirements

DoD requires that all individuals involved in the “design, conduct, or approval of human subjects research” complete human subjects research training. U-M PEERRS human subjects research training, renewed every three years, meets the training requirements for many DoD Components. Investigators are responsible for ensuring that all study team members engaged in the conduct of

human subject research complete PEERRS. The DoD component may evaluate the institution's training program to ensure that personnel are qualified to perform the research, based upon the complexity and risk of the research.

Component specific training:

- Department of Navy (DON) (including Marine Corps)
Principal investigators for projects sponsored by or involving DON Components must complete additional training offered by CITI (www.citiprogram.org), specifically the CITI Training Module for DON-Supported Extramural Performers. Refresher training must be completed every three years. Contact the IRB for assistance with accessing this special training.

This CITI training is also required for institutional and IRB leadership.

The training requirement for other study staff engaged in DON research can be met by either PEERRS or CITI training.

- Secretary of Defense (Personnel and Readiness)
All investigators and research staff on projects sponsored by the Secretary of Defense (Personnel and Readiness) are required to complete annual human subjects protection training. Completion of PEERRS training annually satisfies this requirement.

4.2 Scientific Review

Research involving components of the Army or Navy (including Marine Corps) may require documentation of scientific review prior to IRB review of new applications and substantive amendments.

The scientific review may be the review provided by the funding agency (including DoD), by an established internal review mechanism in the researcher's academic unit, or in the form of an ad hoc review by the researcher's chair or dean. In some cases, the evaluation of scientific merit that is conducted by the IRB as part of its review is sufficient. Check with your IRB or DoD program manager regarding the requirement.

If required, documentation of the scientific review must be provided to the IRB at the time the IRB application is submitted and for substantive amendments. Scientific review must demonstrate that the research uses procedures consistent with sound research design and is likely to yield the expected results and should include the assessment of the following elements:

- Significance of the research question;
- Scientific approach;
- Research team qualifications;
- Facilities and resources available;

The name and qualification of the reviewer(s) should be included as part of the review.

4.3 DoD Approval of Surveys/Interviews

Research involving surveys or interviews with DoD personnel (military or civilian) or their families may require DoD approval. Check with your DoD component regarding any additional review requirements and the timing of the review (before or after IRB review). Provide documentation of this review to the IRB.

4.4 International Research

In its review of the research conducted outside of the United States, the IRB must consider the laws and requirements of the host country as well as the cultural context of the research. This is typically

documented via an in-country or IRB/ethics review and/or a review by a consultant with expertise in that country.

For Navy-sponsored research that involves subjects who are not US citizens or DoD personnel, the investigator must provide the following documentation:

- Permission of the host country; and
- Ethics review and approval by the host country, or the local Naval IRB with host country representation.

4.5 Collaboration with other Institutions

Collaborating institutions in multi-site research must hold a federalwide assurance. Investigators must provide the following:

- Documentation of IRB approval or IRB Authorization Agreement for engaged collaborators;
- Statement of compliance with special DoD requirements (See the U-M DoD addendum).

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

5.1 Prohibited Research

- Research with detainees (prisoners of war), except research with investigational new drugs or devices where such treatment would also be offered to US military service members at the same location and with the same medical condition consistent with established medical practice.

DoD Instruction 2310.01E defines a detainee as: “Any individual captured by, or transferred to the custody or control of, DoD personnel pursuant to the law of war. This does not include persons being held solely for law enforcement purposes, except where the United States is the occupying power. Detainees who are U.S. citizens or U.S. resident aliens will continue to enjoy all applicable rights and privileges under U.S. law and DoD regulations”

- Classified human subjects research: By policy, U-M does not conduct classified research.
- Human testing of chemical or biological agents, except for certain prophylactic, protective or peaceful purposes.

5.2 Definition of “Experimental Subjects”

10 USC 980 provides a special definition for experimental subjects as those included in “an activity, for research purposes where there is intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.”

5.3 DoD Limitations on Waivers of Informed Consent and Consent by LARs

The requirement to obtain consent cannot be waived for any research using DoD funds and meeting the definition of research involving a human being as an experimental subject (10 USC 980). This places limitations on research involving deception, decisionally-impaired individuals, or research being conducted under emergency conditions where the subject may not be able to provide consent.

This statute applies only to certain intervention studies. It does not apply to retrospective research involving analysis of data or specimens, observational studies, blood draws, or tissue collection, and does NOT apply to screening of records to identify possible subjects. The IRB may grant a waiver of consent for such activities.

The Secretary of Defense may waive this consent requirement for 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.

Informed consent may be provided by a legally authorized representative (LAR) only if: (1) the subject lacks decision-making capacity; AND (2) the IRB has determined that the research is intended to be beneficial to the individual subjects.

5.4 Definition of Minimal Risk

The DoD Instruction 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 who has a particular medical condition.

5.5 Research Monitor for More than Minimal Risk Research

A research monitor must be appointed for all research that involves more than minimal risk. The monitor may be either a medical or non-medical monitor depending on the nature of the research. The monitor must be independent of the research team and possess sufficient expertise to evaluate the risks and conduct of the research. The investigator must identify a research monitor by name and have the selection approved by the reviewing IRB. The IRB may choose to appoint more than one monitor for a project and may choose to appoint a monitor for research that is deemed to be no more than minimal risk.

The duties of the monitor are determined based upon the specific risks or concerns associated with each research project. Examples of monitor activities include assessment of subject recruitment and enrollment, data collection or data storage, and analysis. The monitor may be asked to discuss research progress with the investigator, interview subjects, or evaluate adverse events. The monitor has the authority to stop a study in progress, remove participants from the study, or take necessary steps to protect the safety and well-being of participants until the IRB can assess the study.

The IRB must document the required duties and responsibilities of the monitor and communicate this information to the monitor.

The Institutional Official of the DoD Component may waive the requirement for the monitor. The IRB may also choose to appoint a monitor for research that is no more than minimal risk.

5.6 Vulnerable Populations

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. See DoD Instruction 3216.02, Part 7, for a description of additional DoD considerations for these populations. The DoD (and the IRB) considers the need for similar safeguards for other vulnerable populations such as those with cognitive impairment, mental illness, physical disability or any other circumstance that might require special protections.

Section 6 below describes protections for military personnel as research subjects.

5.7 DoD Protections from Medical Expenses if Injured

For more than minimal risk research, the informed consent document must provide information regarding payment of medical expenses, provision of medical care, or compensation for research-related injuries, consistent with the requirements of the Common Rule.

6. DoD Personnel as Research Subjects

6.1 Military Participants

- **Adult Status**
All active duty service members and reserve component members are considered to be adults for the purpose of participating in DoD-conducted or supported research.
- **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 readiness in the field. Investigators may be asked to provide documentation of Command approval as part of the IRB review.
- **Protection of Service Members from Undue Influence**
Officers and senior non-commissioned officers may not influence the decision of subordinates to participate in human subjects research and may not be present at the time of recruitment. Superior officers must be recruited in a separate session from subordinates.

For more than minimal risk research and where recruitment is conducted 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 the same individual appointed by the IRB as the research monitor.

6.2 DoD Civilian Personnel

DoD civilian personnel that are recruited into research are afforded the same protections as military personnel (6.1 above). The requirement for an ombudsman is at the discretion of the IRB.

6.3 Limitations on Compensation

On-duty federal personnel including military members:

- Up to \$50 for blood draws;
- Compensation is not allowed for general research participation.

Off-duty federal personnel including military members:

- Up to \$50 for blood draws;
- Compensation is allowed for general research participation, as approved by the IRB. Payment may not come directly from a federal source. Payment from a federal contractor or non-federal source is permissible.

Non-federal personnel:

- Up to \$50 for blood draws;
- Compensation is allowed for general research participation, as approved by the IRB. Payment may come from a federal or non-federal source.

7. Other DoD-Specific Requirements

7.1 Reporting Requirements

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

- Determinations of serious or continuing noncompliance;
- Unanticipated problems involving risks to subjects or others;
- Study suspensions or terminations;
- Audits, inspections or investigators of DoD research;



- Results of Continuing Review;
- Changes to the reviewing IRB;
- Substantive amendments to the protocol. Amendments must be reviewed and approved by the HRPO prior to implementing the change to the study.

7.2 Recordkeeping

Consistent with U-M policy, research records must be maintained for at least 3 years after the completion of the research. The DoD may require that research records be transferred to the DoD component rather than being retained by U-M.

References*

U-M DoD/Navy Addendum

[Department of Defense – Navy Addendum to the Federalwide Assurance for the Protection of Human Research Subjects, University of Michigan, June 27, 2014.](#)

DoD Regulations and Guidance

[32 CFR 219, Protection of Human Subjects](#)

[DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, November 8, 2011](#)

[10 USC 980, Limitations on the Use of Humans as Experimental Subjects](#)

[Department of Defense Directive 3210.7, Research Integrity and Misconduct](#)

[Department of Defense Directive 6200.2, Use of Investigational New Drugs in Force Health Protection](#)

DoD Component Requirements*

Department of Defense, Office of the Secretary of Defense for Personnel and Readiness

[HA Policy 05.003, Policy for Protection of Human Subjects in Department of Defense Sponsored Research](#)

Department of the Army

[AR 70-25, Use of Volunteers as Subjects of Research, January 25, 1990](#)

[AR 40-38, Clinical Investigation Program, September 1, 1989](#)

[AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, October 19, 2009](#)

Department of the Navy

[SECNAV Instruction 3900.39D, Human Research Protection Program, November 6, 2006](#)

[Department of the Navy, Training and Education Guidance](#)

Department of the Air Force

[Air Force Instruction 40-402, Protection of Human Subjects in Research](#)

* The DoD regulatory and guidance resources cited here are key resources regarding the conduct of DoD-related human subjects research. This is not intended to serve as an authoritative list of all regulations or guidance that may apply to such research. Check with your DoD component for more information.

Attachment A – DoD Components**

- Air Force
- Air Force Academy
- Army
- Army Corps of Engineers
- Coast Guard
- Coast Guard Academy
- Defense Advanced Research Projects Agency (DARPA)
- Defense Intelligence Agency
- Marines
- Military Academy (West Point)
- Missile Defense Agency
- National Geospatial-Intelligence Agency
- National Guard
- National Security Agency
- National War College
- Naval Academy
- Navy
- Office of Naval Research
- Pentagon Force Protection Agency
- Tricare Health System
- U.S. Naval Observatory

** This is not a comprehensive list of DoD Component entities.