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 special requirements for human subjects protections. These special requirements are summarized in this guidance.

   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.

   For DoD-sponsored research, information regarding the specific requirements of the DoD Component should be available from the granting agency.

   Please note that the U-M Office of Research and Sponsored Projects (ORSP) may be required to submit IRB approval to the human subjects protection unit of the DoD funding agency before an award can be activated.

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 (see the list below)
   - The research involves cooperation, collaboration or other type of agreement with a DoD Component, including subawards to the University of Michigan from another institution receiving the direct award from DoD
   - The research uses property, facilities, or assets of a DoD Component
   - 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).

   DoD Components include but are not limited to:

   - 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
3. **Special Requirements for IRB Review of DoD Research**

   Each DoD Component may provide additional guidance about specific requirements. Most of the Component specific requirements are included in this guidance, but PIs are advised to check with the sponsoring Component about any additional requirements.

3.1 **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.

   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.

     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.

3.2 **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.

   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
Documentation of the scientific review must be provided to the IRB at the time the IRB application is submitted. The name and qualification of the reviewer(s) should be included as part of the review.

3.3 DoD Approval of Surveys/Interviews
Research involving the administration of surveys or interviews to DoD personnel (military or civilian) or their families may require DoD approval. Check with the DoD Component regarding any additional review requirements and provide documentation of survey/interview approval or waiver of the review requirement from the DoD Component to the IRB.

3.4 Research Monitor (more than minimal risk research)
A research monitor is required 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 and have the selection approved by the reviewing IRB.

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 Institutional Official of the DoD Component may waive the requirement for the monitor.

3.5 International Research
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.

3.6 Collaboration with other Institutions
Investigators must provide the following information about any collaborating institutions:
- Documentation of IRB approval from engaged collaborators
- Statement of compliance with special DoD requirements (See the U-M DoD addendum)

4. Unique Subject Protections Required for DoD-related Research
4.1 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.
- Classified Human Subjects Research
- Human testing of chemical or biological agents, except for certain prophylactic, protective or peaceful purposes.
4.2 DoD Personnel as Research Subjects

4.2.1 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.

Protection of service members from undue influence
Superiors may not influence the decision of subordinates to participate in human subjects research and may not be present at time of recruitment. Superiors 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 presented clearly, accurately, and adequately and that the voluntary nature of participation is emphasized. The ombudsman may be the same individual appointed by the IRB as the research monitor.

4.2.2 DoD Civilian Personnel

DoD civilian personnel being recruited into research are afforded the same protections as military personnel (4.2.1 above). The requirement for an ombudsman is at the discretion of the IRB.

4.2.3 Limitations on Compensation

On-duty federal personnel including military members
- Up to $50 for blood draws
- No compensation for general research participation

Off-duty federal personnel including military members
- Up to $50 for blood draws
- Compensation for general research participation as approved by the IRB can be paid but not 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 for general research participation as approved by the IRB. Payment may come from a federal or non-federal source.

4.3 Unique DoD Limitations of Waivers of Informed Consent and Consent by Legally Authorized Representatives (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), meaning “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 intervention or interaction.” 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.

4.4 DoD Protections from Medical Expenses if Injured
For more than minimal risk research, subjects must be provided information regarding payment of medical expenses, provision of medical care, or compensation for research-related injuries, consistent with the requirements of the Common Rule.

5. Other DoD-Specific Requirements
5.1 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

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, April 15, 2011

Department of the Air Force

Air Force Instruction 40-402, Protection of Human Subjects in Research

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