



# U-MIC TRANSCRIPT

## Department of Defense Research (Part One)

---

The US Department of Defense has its own regulations governing research that involves any component of the Department of Defense. The University of Michigan has signed a special addendum to its Federalwide Assurance to incorporate these additional Department of Defense and Department of Navy requirements.

Department of Defense components include:

- the Army;
- the Navy;
- the Air Force;
- the Marines;
- the Coast Guard;
- and
- numerous academies, offices, and agencies.

These regulations, which appear in the Code of Federal Regulations at 32 CFR 219, apply to research involving:

- funding;
- cooperation, collaboration, or other agreements;
- property, facilities, or assets;
- or
- personnel

of a Department of Defense component. Although these regulations may not apply to all studies whose subjects include individuals affiliated with a Department of Defense component, any study that *intentionally* recruits and enrolls Department of Defense personnel is subject to these regulations.

If Department of Defense–related research presents more than minimal risk, the researcher must appoint a study monitor with appropriate medical or other expertise, and must identify that monitor, by name, in the study protocol. The monitor, who reports all concerns directly to the IRB, oversees study activity to ensure subject safety, and has the authority to remove subjects from the study or to halt the research.

Department of Defense regulations permit an IRB to grant a waiver of informed consent only during a study's preliminary screening phase or during retrospective analysis. For all other study activity, the researcher must obtain consent from all subjects, unless the head of the Department of Defense component involved in the research has granted a waiver.

# U-MIC TRANSCRIPT

## Department of Defense Research (Part One)

According to Department of Defense regulations, a legally authorized representative may provide informed consent on behalf of a subject unable to consent for him or herself *only* if the IRB has determined that the research is likely to offer direct benefit to study subjects.

Researchers conducting Department of Defense–related studies may need to undergo more research education and training than the University of Michigan ordinarily requires. For example, principal investigators for projects sponsored by or involving Department of the Navy components must complete the CITI Training Module for DoN-Supported Extramural Performers, as well as a refresher course every three years.

For Navy-sponsored research that involves subjects who are not US citizens or Department of Defense personnel, the researcher must document:

- The permission of the host country  
and
- Ethics review and approval by the host country or a local Naval IRB that represents the host country

Research involving surveys or interviews with personnel or their families may require Department of Defense approval. Researchers should check with the Department of Defense component in question regarding additional requirements, and should provide the IRB with documentation of the component’s approval.

Since some research might impact a soldiers’ readiness in the field, researchers may need to obtain and document command approval before enrolling military personnel in a study.

Department of Defense regulations expressly prohibit:

- Research on prisoners of war, except for drug or device studies involving treatments that would be offered to US military service members with the same medical conditions and under the same circumstances;
- Classified human subjects research ;  
and
- Human testing of chemical or biological agents, except for certain preventive, protective, or peaceful purposes.

Research involving components of the Army or Navy (including the Marine Corps) may require scientific review prior to IRB review of initial study applications or amendments. This review may be carried out

# U-MIC TRANSCRIPT

## Department of Defense Research (Part One)

by:

- the funding agency (including the Department of Defense);
  - an established internal review mechanism within the researcher's academic unit;
- or
- the researcher's chair or dean.

This review must establish that the study is properly designed and likely to yield the expected results, and should assess:

- the significance of the research question;
  - the scientific approach;
  - the study team's qualifications;
- and
- the available facilities and resources.

The researcher should submit documentation of the scientific review, indicating the reviewers' names and qualifications, with the IRB application.

The regulations set limits on the compensation that subjects may receive for participating in Department of Defense–related research.

- No subject may receive more than \$50 for blood draws.
- On-duty federal personnel, including military members, may not receive any compensation for general study participation.
- Off-duty federal personnel may receive compensation for participation, but compensation may not come directly from a federal source.

Non-federal personnel participating in Department of Defense–related research may receive compensation for general study participation, and this may come from a federal or non-federal source. The IRB is responsible for approving the compensation amount.

Contact the IRB for more information about federal regulations governing Department of Defense–related research.

*Posted: 9/6/2012*