



U-MIC TRANSCRIPT Department of Defense Research (Part Two)

Department of Defense regulations define “research involving a human being as an *experimental subject*” as:

an activity for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects....This definition does not include...research involving the collection or study of existing data, documents, records, or specimens from living individuals.

Non-interventional studies, or studies not designed to base conclusions directly on researcher-subject interactions, may involve participation by human subjects, though not by experimental subjects, according to the Department of Defense definition. For example, individuals whose participation consists solely of providing blood or tissue samples for use in Department of Defense–related research are human subjects, but not experimental subjects.

Department of Defense regulations permit a legally authorized representative to provide informed consent on behalf of an experimental 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.

Federal requirements for research involving vulnerable populations, covered in subparts B, C, and D of the Department of Health and Human Services’ regulations, also apply to Department of Defense–related research. These special requirements pertain to studies whose subjects include:

- pregnant women, fetuses, and some newborns;
 - prisoners;
- and
- children.

As part of protecting service member subjects and potential subjects from undue influence, researchers must take measures to prevent superiors from influencing subordinates’ decisions about participating in Department of Defense–related research. Such measures include both

U-MIC TRANSCRIPT
Department of Defense Research
(Part Two)

recruiting and obtaining informed consent from subordinate service members while no superiors are present.

If a study initially approved by a convened IRB becomes Department of Defense–related through an amendment, the IRB should approve the amendment by convened Board, as well, since the research is now subject to Department of Defense regulations.

When reviewing a continuing review application for Department of Defense–related research, the IRB should verify that the researchers:

- have met all applicable requirements for continuing education and training;
- and
- have provided the IRB with copies of any publications, presentations, or reports that have resulted from the research.

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

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