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MEMORANDUM FOR DIRECTOR OF BIOLOGICAL SYSTEMS, OFFICE OF THE  
DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING

SUBJECT: Applicability of Human Research Subject Protections to Certain Activities

This responds to your request for an opinion on the applicability of 10 U.S.C 980, DoD Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002, and 32 CFR Part 219, "Protection of Human Subjects," to certain activities in which some scientific methods are used, but which may not constitute human subjects research. Such activities include health surveillance, medical quality assurance, program evaluations, use of pre-existing data sets, customer satisfaction surveys, operational testing, and demonstration projects.

10 U.S.C. 980 prohibits, subject to very limited exceptions, the use of DoD funds for "research involving a human being as an experimental subject" except with the informed consent of the subject. Section 980 applies only to the Department of Defense. 32 CFR Part 219 is DoD's adoption of the landmark, government-wide "Common Rule" for the protection of human research subjects. The Common Rule requires Institutional Review Board approval of human subject research and informed consent for such research, subject to waiver in certain cases involving minimal risk. The Department of Health and Human Services is the lead agency for the Common Rule. DoD Directive 3216.2 is part of DoD's implementation of both section 980 and the Common Rule.

Section 980's command applies to "research involving a human being as an experimental subject." This term is not defined in the statute but is defined in DoD Directive 3216.2 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." ¶ E2.1.3. "Research" is also not defined in the statute, but is defined in both the Common Rule and the DoD Directive as a "systematic investigation . . . designed to develop or contribute to generalizable knowledge." DoDD 3216.2, ¶ E2.1.2; 32 CFR 219.102(d).

The term "systematic investigation" is not further defined in the Common Rule or Directive. The best source of understanding this term is the Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Federal Register 23192, April 18, 1979, on which the main principles of the Common Rule are based. The Belmont Report states (in Part A):



“[T]he term ‘research’ designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.”

For purposes of applying the definition of “research,” the term “systematic investigation” should be understood to mean such activity.

In attempting to accomplish the purpose of section 980’s prohibition on non-consensual research “involving a human being as an experimental subject,” DoD Directive 3216.2 refers to “an intervention or interaction,” and provides several examples, but does not specifically address whether routine interactions, such as filling out government forms, are included. The Directive (§ E2.1.3.4) does, however, exempt from the definition of “research involving a human being as an experimental subject” activities exempt under the Common Rule. This is consistent with the legislative history of section 980, which indicates that routine and standard interactions with individuals are not the subject of the statutory prohibition.<sup>1</sup>

Based on these points, research involving a human being as an experimental subject should be understood as an activity with all of the following attributes:

- There is a non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.
- It is part of a systematic investigation to test an hypothesis and permit conclusions to be drawn, usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.
- Its overall primary purpose is to contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

It should be noted that the scope of applicability of section 980, which addresses only the issue of informed consent, is not the same as the scope of applicability of the Common Rule, which addresses many other issues and allows for waivers of informed consent for some minimal risk research. The Common Rule, for example, also applies to some research involving pre-existing data bases, even though it is not research involving a human being as an experimental subject. Of course, DoD is obliged to comply with the Common Rule requirements.

<sup>1</sup> Section 980 was enacted in 1984, Pub. L. 98-525, § 1401(c)(1), as a codification of previously enacted, recurring general provisions in annual appropriations Acts, dating back to 1972, Pub. L. 92-570, § 745. The legislative history of that first provision is in the Congressional Record of October 2, 1972, pages 33153 – 33164.

With these principles as the guide, several DoD activities can be considered to determine if they are subject to section 980 and the Common Rule.

- Health surveillance. This refers to activities such as those carried out under 10 U.S.C. 1074f (medical tracking system for members deployed overseas). Health surveillance is part of the medical care and public health care functions of the Military Health System. It is not human subjects research under section 980 and the Common Rule. Thus, it is permissible to require military personnel to participate in health surveillance activities.
- Medical quality assurance. This refers to activities such as those covered by 10 U.S.C. 1102 and DoD Directive 6025.13, "Medical Quality Assurance in the Military Health System," May 4, 2004. Although it may employ scientific methods of review, it is not for research purposes under the criteria identified above. Therefore, neither section 980 nor the Common Rule apply.
- Program evaluation. This refers to assessments of the success of established programs in achieving objectives when the assessments are for the use of DoD program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. This is not for research purposes under the criteria discussed above. However, if it were an assessment carried out for publication in general literature regarding non-DoD programs of a similar type, it would be for a research purpose.
- Customer satisfaction surveys. This refers to surveys of program users to obtain feedback for use by program managers. This is similar to program evaluation. These surveys for use by program managers do not share the attributes of human subject research.
- Research using pre-existing data sets. This refers to uses of pre-existing data sets, including those with personally identifiable information. As discussed above, it is not research involving a human being as an experimental subject for purposes of section 980. It may, however, still be research covered by the Common Rule because based on identifiable private information. It may also be covered by DoD 6025.18-R, "Health Information Privacy Regulation," January 2003.
- Operational test and evaluation. This refers to activities defined in DoD Directive 5141.2, "Director of Operational Test and Evaluation (DOT&E), May 25, 2000, as: "The field test, under realistic conditions, of any item (or key component) of weapons, equipment, or munitions for the purpose of determining the operational effectiveness and operational suitability of the weapons, equipment, or munitions for operational use, including combat, by typical military users, and the evaluation of the results of such test." If the purpose of the test is to obtain data on the effects of non-routine interaction with an individual, it would be human subjects research. If the purpose is to make other types of assessments regarding the attributes of the weapon, equipment, or munitions, it would not be human subjects research.

- **Demonstration projects.** This refers to activities such as those carried out under 10 U.S.C. 1092. Demonstration projects designed to study public benefit programs are exempt under the Common Rule (32 CFR 219.101(b)(5)) and DoD Directive 3216.2 (¶ E2.1.3.4). However, a project for the purpose of testing the effects on individuals of a non-standard medical therapy would not be exempt.

As is evident from this review, an assessment of the applicability of 10 U.S.C. 980, the Common Rule, and DoD Directive 3216.2 requires a careful consideration of the purpose and other attributes of the activity. To aid in this careful consideration, although not a legal mandate, it may be an advisable management practice for DoD components or commands, whenever there is a close call on whether an undertaking is covered by these requirements, to seek the advice of an established IRB.



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