The Case for the Repeal of 10 U.S.C. § 980

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1. Introduction

Title 10 U.S.C. § 980[1]—which limits the use of Department of Defense (DoD) funds for research involving human experimental subjects—is a redundant and unnecessary law that adds no extra protections for participants. Its continued existence only complicates the DOD review process and research partnerships without offering any real benefit to human safety. Congress should repeal it. The protection of human subjects in research is a vital ethical and legal duty, overseen by a comprehensive and evolving federal regulatory system. This system, primarily made up of the Common Rule (45 CFR Part 46), Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56), and the Health Insurance Portability and Accountability Act (HIPAA), already sets strict standards for informed consent, Institutional Review Board (IRB) oversight, and data privacy.

2. Historical Context:

While 10 U.S.C. § 980 is now unnecessary, it is important to recognize its historical role. This provision was added to the U.S. Code on October 19, 1984, and took effect on October 1, 1985. At the time it was enacted, the broader federal regulatory environment for human subjects research was still developing.

- **Early HHS Regulations:** Basic rules for human subjects research supported or conducted by the Department of Health, Education, and Welfare (now HHS) were first published in 1974. However, the comprehensive "Federal Policy for the Protection of Human Subjects," informally known as the "Common Rule" (45 CFR Part 46, Subpart A), which unified regulations across multiple federal agencies, was not published and officially adopted until 1991.
- **Emerging FDA Regulations:** Although the FDA issued a final rule for 21 CFR Part 50 on informed consent in July 1981, its comprehensive set of regulations for Institutional Review Boards (21 CFR Part 56) was mainly implemented in 1991. Efforts to align HHS and FDA regulations continue, but notable differences still exist.
- **Lack of HIPAA:** The Health Insurance Portability and Accountability Act (HIPAA), which set detailed standards for health information privacy and security, was not enacted until August 1996.

Therefore, in 1985, 10 U.S.C. § 980 served as an important legal safeguard. It explicitly required informed consent for DoD-funded interventional human research at a time when broader, more detailed, and consistent federal regulatory frameworks were still developing or not yet widely adopted. It addressed a crucial gap by legally instilling a fundamental ethical principle for military research subjects classified as “experimental subjects,” adding a layer of protection that was not yet common across all federal research.

3. Current Regulatory Framework

The existing federal regulatory landscape for human subjects research is designed to be

exhaustive and adaptable, ensuring ethical conduct across diverse research settings and populations.

A. The Common Rule (45 CFR Part 46)
The Federal Policy for the Protection of Human Subjects, known as the Common Rule (45 CFR Part 46), serves as the core guideline for safeguarding human subjects in federally funded research. It outlines key provisions for IRBs, informed consent, and Assurances of Compliance. In addition to its main requirements (Subpart A), the Common Rule offers extra protections for vulnerable groups: pregnant women, human fetuses, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D). Institutions conducting federally supported research must obtain a Federalwide Assurance (FWA) from the Office for Human Research Protections (OHRP), documenting agreement to comply with these regulations.

B. FDA Regulations (21 CFR Parts 50 & 56)
The FDA regulates clinical investigations involving products under its jurisdiction (e.g., drugs, biologics, medical devices), regardless of funding source. Key regulations, 21 CFR Part 50 (Informed Consent) and 21 CFR Part 56 (IRBs), ensure the protection of subjects' rights and welfare in biomedical research. FDA regulations also include specific safeguards for children in clinical investigations.

C. HIPAA Privacy and Security Rules
The HIPAA Privacy Rule (45 CFR Part 164, Subpart E) sets national standards for how "covered entities" use and disclose Protected Health Information (PHI) for research, requiring either individual authorization or a waiver approved by an IRB or Privacy Board. The HIPAA Security Rule (45 CFR Part 164, Subpart C) mandates administrative, physical, and technical safeguards for electronic PHI (ePHI). These rules are enforced by the Office for Civil Rights (OCR).

4. Current Context

Despite its historical necessity, 10 U.S.C. § 980 is now entirely redundant considering the existing, comprehensive human research protection regulations:

A. Informed Consent is Required for Greater than Minimal Risk Studies:
The main requirement of 10 U.S.C. § 980 is obtaining advanced informed consent for DOD-funded interventional research with human subjects. However, both the Common Rule (45 CFR Part 46) and FDA regulations (21 CFR Parts 50 & 56) already set detailed and strict standards for advanced informed consent in nearly all interventional human subjects research conducted or supported in the U.S. These regulations specify the elements of consent, how to obtain it, and the necessary documentation, which go far beyond the simple statement in 10 U.S.C. § 980. The revised Common Rule also requires a "concise and focused presentation of key information" to enhance understanding.

B. Waiver Provisions are More Stringent and Comprehensive Elsewhere:
10 U.S.C. § 980 allows the Secretary of Defense to waive the consent requirement under

specific conditions, including when there is a direct benefit to the subject, the medical product is intended for the armed forces, and all other applicable laws are followed. Both the Common Rule and FDA regulations specify detailed, ethically based criteria for waiving or modifying informed consent requirements. These criteria generally require that the research involves minimal risk, cannot be practically conducted without the waiver, and will not harm subjects' rights or welfare. These waiver provisions are more detailed and protective, ensuring that any deviation from full consent is ethically justified and thoroughly reviewed by an IRB.

5. Conclusion

10 U.S.C. § 980 highlights a key requirement—informing participants and obtaining their consent—which federal human research regulations already cover more thoroughly and stringently. It does not add any new or extra protections for participants beyond those mandated by 45 CFR Part 46 and 21 CFR Parts 50 and 56. Its ongoing inclusion in the U.S. Code results in unnecessary duplication and complicates regulation without providing any real benefit to human subjects.

Repealing 10 U.S.C. § 980 would simplify the legal and administrative framework for human research, improving clarity and efficiency for institutions and investigators involved in DoD-funded research. Repeal would support the administration’s goal of deregulation. Most importantly, this change would not weaken protections for human subjects, as current federal regulations already provide a strong and adaptable system of ethical oversight. Therefore, to enhance regulatory clarity, efficiency, and promote ongoing ethical research development, 10 U.S.C. § 980 should be repealed.

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[1] 10 USC 980: Limitation on use of humans as experimental subjects, Accessed September 7, 2025, https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section980&num=0&edition=prelim