

THE MILITARY BIOMEDICAL COMPLEX: ARE SERVICE MEMBERS A VULNERABLE POPULATION?

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INTRODUCTION

In the realm of research with human subjects, vulnerability is an elusive concept. Its essence lies in an asymmetry – of information, access, status, power, or control. Yet vulnerability is also context-dependent, meaning a person becomes vulnerable *to* something when placed in a certain situation. While there is widespread agreement that research guidelines should provide protections for those who are vulnerable, there is less consensus on who is encompassed by the term and what protections are appropriate.¹ In the United States, regulatory guidelines take a categorical approach to defining vulnerability – federal protections identify prisoners, children, neonates, human fetuses, and pregnant women as vulnerable populations, and specify additional protections for research that includes participants from

¹ See Carl H. Coleman, *Vulnerability as a Regulatory Category in Human Subject Research*, 37 J.L. MED. & ETHICS 12 (2008).

these groups.² This Article examines the notion of vulnerability in human subjects research as it applies to members of the armed forces.³

The armed forces maintain a unique and important role in society. As the United States Department of Defense (“DoD”) indicates, its primary objective is to “provide the military forces needed to deter war and to protect the security of the United States.”⁴ An indispensable component of the military mission is military medicine, whose fundamental goal is to conserve the fighting force via preventive medicine and health care for combat-related injuries.⁵ As science and warfare have evolved, however, military medical personnel have taken on additional responsibilities, including work related to the research and development of cutting-edge weaponry.⁶ According to Brigadier General Dr. Stanhope Bayne-Jones, this has created “a serious moral and practical problem” whereby roles and fiduciary duties of military physicians and researchers oftentimes conflict in irreconcilable ways.⁷

The impact on service members has been striking. In the name of national security, the U.S. military locked service members in gas chambers and exposed them to mustard gas against their will,⁸

² See 45 C.F.R. § 46 (2015). While the statute also states that “mentally disabled persons” and “economically or educationally disadvantaged persons” are examples of vulnerable populations, the regulations do not set forth additional protections, or a separate Subpart, specific to these groups. Rather, the Common Rule provides general guidance that directs institutional review boards (“IRBs”) to consider protections that “protect the rights and welfare of these groups.” *Id.* § 46.111.

³ For purposes of this Article, I use the terms “members of the armed forces,” “service members,” and “military personnel” interchangeably.

⁴ *Our Bottom Line*, U.S. DEP’T OF DEF. (Aug. 29, 2015), <http://www.defense.gov/About-DoD/DoD-101#Our%20Bottom%20Line>.

⁵ See Mike Mitka, *US Military Medicine Moves to Meet Current Challenge*, 286 JAMA 2532, 2532–33 (2001) (describing battlefield medical priorities).

⁶ *Id.*

⁷ STANHOPE BAYNE-JONES, *THE EVOLUTION OF PREVENTIVE MEDICINE IN THE UNITED STATES ARMY: 1607-1939*, at 157–58 (1968). Dr. Bayne-Jones was Deputy Chief of the Preventive Medicine Service in the U.S. Office of the Surgeon General during World War II. While his comments were in the context of research related to atomic, biological, and chemical weapons, his observations are no less relevant today. See *id.*

⁸ See Susan L. Smith, *Mustard Gas and American Race-Based Human Experimentation in World War II*, 36 J.L. MED. & ETHICS 517, 517 (2008).

ordered pilots to fly into atomic clouds minutes after a nuclear explosion to test the rate of absorption of radiation,⁹ and surreptitiously administered LSD and other psychotropic drugs to examine the products as tools for interrogations or chemical weapons.¹⁰ Military officials often threatened service members and veterans with prosecution if they revealed the existence of these studies.¹¹ In some instances, the U.S. government refused to provide compensation or adequate medical care to address research-related injuries.¹² As with groups who have been exploited in other research-related contexts,¹³ these actions have had a lasting impact on the willingness of service members to trust that their government is being truthful and reasonable in its balancing of the concerns of military personnel with national security priorities.¹⁴

More recently—and particularly as the fields of genomics, neuroscience, computer science, and nanotechnology have advanced—the military biomedical complex has expanded the breadth and depth of its research via classified and unclassified projects involving hospitals, universities, and private entities.¹⁵ Many

⁹ See FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS 469 (Oxford Univ. Press 1996).

¹⁰ See David H. Price, *Buying a Piece of Anthropology*, 23 ANTHROPOLOGY TODAY 8, 8–9 (2007).

¹¹ See, e.g., Efthimios Parasidis, *Justice and Beneficence in Military Medicine and Research*, 73 OHIO ST. L.J. 724, 733 (2012) (describing the U.S. government's actions in the context of service members who participated in the mustard gas experiments).

¹² See, e.g., *id.*

¹³ The exploitation of poor, rural African-Americans during the Tuskegee Syphilis Study is one example. See, e.g., JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* 220 (1993) (“No scientific experiment inflicted more damage on the collective psyche of black Americans than the Tuskegee Study.”).

¹⁴ See, e.g., Patrick Cockburn, *U.S. Navy Tested Mustard Gas on Its Own Sailors*, INDEPENDENT (Mar. 13, 1993), <http://www.independent.co.uk/news/world/us-navy-tested-mustard-gas-on-its-own-sailors-in-1943-the-americans-used-humans-in-secret-1497508.html> (“The bitterness of the veterans who were used as guinea pigs . . . stems from the refusal of the armed forces to acknowledge what had happened to them.”); Caitlin Dickerson, *Secret World War II Chemical Experiments Tested Troops by Race*, NPR (June 22, 2015), <http://www.npr.org/2015/06/22/415194765/u-s-troops-tested-by-race-in-secret-world-war-ii-chemical-experiments>; Caitlin Dickerson, *The VA's Broken Promise to Thousands of Vets Exposed to Mustard Gas*, NPR (June 23, 2015), <http://www.npr.org/2015/06/23/416408655/the-vas-broken-promise-to-thousands-of-vets-exposed-to-mustard-gas>.

¹⁵ Classified research “poses particular challenges for IRBs [institutional review boards].” Paul

projects have been spearheaded by the Defense Advanced Research Projects Agency (“DARPA”), which has invested billions of dollars to facilitate “breakthrough technologies for national security.”¹⁶ Projects include: (1) developing drugs that can reduce fear, increase aggressiveness, or keep individuals awake and alert for up to seven days straight; (2) genetically engineering the human immune system so that it is able to recognize and adapt to any pathogen; (3) creating implantable electrodes that permit human-to-human and human-to-computer communication via thought alone; and (4) establishing human-to-computer interfaces that are able to detect a person’s neurological state and release neurochemicals that can combat fatigue, enhance mood, suppress or improve memory, or facilitate learning.¹⁷ The goal of this research is to create warfighters that have superior physical, physiological, and cognitive abilities.¹⁸ As DARPA explains, “the Agency must be fearless about exploring new technologies and their capabilities.”¹⁹

Re-examining the regulatory framework governing research involving service members is both timely and prudent. The Office for Human Research Protections (“OHRP”) and the U.S. Department of Health and Human Services (“HHS”) are in the midst of revising the

J. Amoroso & Lynn L. Wenger, *The Human Volunteer in Military Biomedical Research*, in 2 MILITARY MEDICAL ETHICS 563, 595 (Thomas E. Beam & Linette R. Sparachino eds., 2003). As Amoroso and Wenger explain, “[h]istorically, some of the DoD’s worst transgressions in ethical treatment of human subjects have arisen from studies that were kept secret in the interest of national security.” *Id.*

¹⁶ DARPA, <http://www.darpa.mil> (last visited Jul. 5, 2016); see also *Breakthrough Technologies for National Security*, DARPA (Mar. 2015), <http://www.darpa.mil/attachments/DARPA2015.pdf>.

¹⁷ For project details, see Catherine L. Annas & George J. Annas, *Enhancing the Fighting Force: Medical Research on American Soldiers*, 25 J. CONTEMP. HEALTH L. & POL’Y. 283, 283–308 (2009); Michael N. Tennison & Jonathan D. Moreno, *Neuroscience, Ethics, and National Security: The State of the Art*, 10 PLOS BIOLOGY 1, 1 (2012); Jonathan D. Moreno, *Juicing the Brain: Research to Limit Mental Fatigue Among Soldiers May Foster Controversial Ways to Enhance Any Person’s Brain*, 17 SCI. AM., Dec. 2006, at 66, 66–73; Hannah Hoag, *Neuroengineering: Remote Control*, 423 NATURE 796, 796–98 (2003); Michael H. Bonnet et al., *The Use of Stimulants to Modify Performance During Sleep Loss: A Review by the Sleep Deprivation and Stimulant Task Force of the American Academy of Sleep Medicine*, 29 SLEEP 1163, 1176–80 (2005).

¹⁸ TONY TETHER, DEF. ADVANCED RESEARCH PROJECTS AGENCY, STATEMENT TO THE SUBCOMMITTEE ON TERRORISM, UNCONVENTIONAL THREATS AND CAPABILITIES 11 (2003).

¹⁹ *Breakthrough Technologies for National Security*, *supra* note 16, at 6.

federal guidelines for human subjects research—the first such undertaking since the regulations were promulgated in 1991.²⁰ Considerable public comment and debate followed publication of HHS's Advance Notice of Proposed Rulemaking ("ANPRM")²¹ and its Notice of Proposed Rulemaking ("NPRM").²² Both the ANPRM and NPRM underscore the disruptive advancements in science over the past few decades and the need to amend the law to keep pace with science and research.²³ In addition, military physicians have highlighted the importance of critically examining military medical ethics and have acknowledged that such debate "could challenge even our most basic presuppositions and that these challenges would cause discomfort."²⁴

I begin my inquiry with two fundamental questions: (1) what is research? and (2) what does it mean for a research subject to be vulnerable? I then examine markers of vulnerability for service members. These include military command structure, a nebulous boundary between treatment and research in military settings, informed consent waivers for military personnel, military culture, the predominance of force health priorities over individual health concerns, and governmental immunities related to claims by service members for research-related injuries. I analyze the extent to which current laws and guidelines treat service members as a vulnerable

²⁰ See *NPRM for Revisions to the Common Rule: HHS Announces Proposal to Improve Rules Protecting Human Research Subjects*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html> (last visited Mar. 25, 2016).

²¹ Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512 (proposed July 26, 2011) [hereinafter ANPRM] (to be codified at 45 C.F.R. pt. 46, 160, 164).

²² Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933 (proposed Sept. 8, 2015) [hereinafter NPRM] (to be codified at 45 C.F.R. pt. 46).

²³ See, e.g., *id.* at 53,935; ANPRM, *supra* note 21, at 44,513.

²⁴ Victor W. Sidel & Barry S. Levy, *Physician-Soldier: A Moral Dilemma?*, in 1 MILITARY MEDICAL ETHICS 563, 595 (Thomas E. Beam & Linette R. Sparachino eds., 2003). The quoted passage was written by the editors of the landmark treatise, *Military Medical Ethics*, which is published by the Borden Institute under the aegis of The Surgeon General of the U.S. Army. The Borden Institute is based in the Walter Reed Army Medical Center, and the aforementioned editors are professors of medicine at the F. Edward Hebert School of Medicine at the Uniformed Services University of the Health Sciences.

population, consider the legal, societal, and policy implications of categorizing service members as a vulnerable population under federal law, and conclude by suggesting amendments to the federal guidelines and highlighting areas that would benefit from additional public discourse. Military medical ethics is a growing field, and my goal is to add to the literature by proposing ideas that balance principles of medical ethics, national security, and the rights of service members.

I. VULNERABLE POPULATIONS: THE COMMON RULE AND SUBPARTS B-D

U.S. guidelines governing research with human subjects are codified in 45 C.F.R. Part 46, which is titled “Protection of Human Subjects.”²⁵ Among these regulations, Subpart A (“Basic HHS Policy for Protection of Human Research Subjects”) is often referred to simply as the Common Rule.²⁶ Fifteen federal agencies and departments have adopted the Common Rule, including the DoD and the U.S. Department of Veterans Affairs (“VA”).²⁷ Pursuant to Executive Order 12333, the Intelligence community, including the Central Intelligence Agency (“CIA”) and the Office of the Director of National Intelligence (“ODNI”), must adhere to the Common Rule.²⁸

Under the Common Rule, there are three primary mechanisms for protecting research subjects: informed consent; review by an institutional review board (“IRB”); and institutional assurances of compliance with federal policies.²⁹ Among its provisions, the Common Rule requires that risks to research subjects be minimized, that the selection of research participants be fair, and that risks to participants be reasonable in relation to the anticipated benefits of the research.³⁰

²⁵ 45 C.F.R. § 46 (2015).

²⁶ See *Federal Policy for the Protection of Human Subjects* (‘Common Rule’), U.S. DEPT HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (last visited May 18, 2016).

²⁷ See *id.* (providing a list of the agencies and departments).

²⁸ Exec. Order No. 12,333, 46 Fed. Reg. 59,941 (Dec. 4, 1981).

²⁹ 45 C.F.R. §§ 46.101–46.124.

³⁰ *Id.*

Additional protections for certain categories of vulnerable populations are codified in Subpart B (pregnant women, human fetuses, and neonates), Subpart C (prisoners), and Subpart D (children).³¹ Some departments and agencies that have adopted the Common Rule have not adopted the additional Subparts via regulation, while others have incorporated the protections of the Subparts via agency policy.³² For example, the DoD and VA have not adopted Subparts B, C, and D by regulation, but have adopted the protections outlined in these Subparts as a matter of policy.³³ Via Executive Order, the CIA and Intelligence community are bound by Subparts B, C, and D.³⁴

In contemplating whether, in the context of human subjects research, service members are a vulnerable population, two general inquiries must first be addressed: (1) what activities constitute research with human subjects? and (2) for purposes of human subjects research, what does it mean to be vulnerable?

A. When Do Research Protections Apply?: Distinguishing Medical Treatment from Research with Human Subjects

The Common Rule and related Subparts apply solely to research involving human subjects.³⁵ They have no legal significance for the

³¹ In addition, Subpart E outlines regulations governing the registration of IRBs. Subpart E does not contain any guidelines that are specific to research involving vulnerable populations.

³² See *Frequently Asked Questions*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/policy/faq/45-cfr-46/common-rule-human-subjects.html> (last updated Feb. 16, 2016).

³³ See U.S. DEP'T OF DEF., DOD AND OUSD(P&R) SPECIFIC AND UNIQUE REQUIREMENTS, § 1.2.1 (titled, "DoD Human Subjects Regulations: Applicability of the Subparts"); DEP'T OF VETERANS AFFAIRS, VETERANS HEALTH ADMIN., *Requirements for the Protection of Human Subjects in Research*, in VETERANS HEALTH ADMINISTRATION HANDBOOK 1200.05, at 1 (2014). In addition to the DoD guidelines, branches of the armed forces have promulgated policies that require compliance with Subparts B–D. See, e.g., *20 FAQs About Human and Animal Research*, OFF. OF NAVAL RESEARCH, <http://www.onr.navy.mil/en/About-ONR/compliance-protections/Research-Protections/Research-Protection-FAQs.aspx> (last visited Mar. 25, 2016) (indicating that it is Navy policy to follow Subparts B, C, and D).

³⁴ See Exec. Order No. 12,333, 46 Fed. Reg. 59,941, § 2.10 (Dec. 4, 1981) (indicating that the intelligence community must adhere to the guidelines issued by the HHS regarding human subjects research, and not providing for an exception to any Subpart thereof).

³⁵ 45 C.F.R. § 46.101(a) (2015).

practice of medicine or in non-research settings.³⁶ Under the Common Rule, “research” is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”³⁷ Drawing a line between medical treatment and research has proven to be difficult in both theory and practice, although there are several factors that help mark the boundary.

As with many areas in human subjects research, the Belmont Report³⁸ provides a particularly relevant starting point in distinguishing between medical treatment and research. Published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (“National Commission”), the Belmont Report is the preeminent normative framework for U.S. guidelines governing human subjects research.³⁹ Drafted in the wake of public disclosure of various research-related scandals—including Tuskegee and the military’s secret LSD, mustard gas, and biological warfare experiments⁴⁰—the Belmont Report identifies three fundamental ethical principles that underlie research with human subjects: respect for persons; beneficence; and justice.⁴¹ The Belmont Report also highlights the distinction between treatment and research, and why this distinction is important.⁴² As the Belmont

³⁶ *Id.* § 46.101(e).

³⁷ *Id.* § 46.102(d).

³⁸ THE NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter *The Belmont Report*].

³⁹ See generally Amy L. Davis & Elisa A. Hurley, *Setting the Stage: The Past and Present of Human Subjects Research Regulation*, in HUMAN SUBJECTS RESEARCH REGULATION: PERSPECTIVES ON THE FUTURE 10–11 (I. Glenn Cohen and Holly F. Lynch eds., MIT Press 2014) (discussing the major regulatory changes to the Common Rule proposed in the June 2011 ANPRM).

⁴⁰ See JONES, *supra* note 13, at 36; Parasidis, *supra* note 11, at 731–40.

⁴¹ The Belmont Report, *supra* note 38, at 1. Among its provisions, the National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (“National Commission”). One of the National Commission’s mandates was “to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.” *Id.*

⁴² *Id.*

Report explains, treatment includes “interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success,” while research encompasses “an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge.”⁴³

While the framework outlined in the Belmont Report succinctly distinguishes between treatment and research, there is a long line of scholarship that highlights its shortcomings.⁴⁴ For example, when a physician departs from standard practice or applies an innovative therapy, does this departure constitute research? As bioethicist Baruch Brody explains, the authors of the Belmont Report struggled with this predicament.⁴⁵ After all, medicine is both science and art, and innovation in medicine invariably relies upon risk-taking and the ability to contemplate and carry out novel solutions to unanswered questions. Indeed, at one level, “every physician is carrying out a small research project when he [or she] diagnoses and treats a patient.”⁴⁶ That said, from a regulatory perspective, there must be a meaningful distinction between treatment and research.

In the end, the Belmont Report suggests that a medical procedure can be experimental (insofar as the procedure departs from standard care or is innovative), but that implementation of an experimental procedure does not necessarily constitute research.⁴⁷ At the same time, the Belmont Report indicates that a “radically” new procedure or

⁴³ *Id.*

⁴⁴ See, e.g., Ruth W. Grant & Jeremy Sugarman, *Ethics in Human Subjects Research: Do Incentives Matter?*, 29 J. MED. & PHILOSOPHY 717 (2014); Carol Levine et al., *The Limitations of “Vulnerability” as a Protection for Human Research Participants*, 4 AM. J. BIOETHICS 44 (2008); Richard B. Miller, *How the Belmont Report Fails*, 4 ESSAYS PHILOSOPHY 1 (2003); Anna Mastroianni & Jeffrey Kahn, *Swinging the Pendulum: Shifting Views of Justice in Human Subjects Research*, 31 HASTINGS CTR. REP. 21 (2001); BARUCH A. BRODY, *THE ETHICS OF BIOMEDICAL RESEARCH* (Oxford Univ. Press 1998).

⁴⁵ BRODY, *supra* note 44, at 37.

⁴⁶ Tim Lewens, *Distinguishing Treatment From Research: A Functional Approach*, 32 J. MED. ETHICS 424, 425 (2006) (quoting Dr. Thomas Chalmers).

⁴⁷ The Belmont Report, *supra* note 38, at 3.

“major innovation” should be the subject of clinical research prior to adoption as medical treatment.⁴⁸

More recently, the U.S. Food and Drug Administration (“FDA”) has outlined ten categories that help draw the line between treatment and research:⁴⁹

	Clinical Research	Medical Treatment
Intent	Answers specific questions through research involving numerous research volunteers.	Addresses the needs of individual patients.
Intended Benefit	Generally designed and intended to benefit future patients.	Intended to benefit the individual patient.
Funding	Paid for by drug developers and Government agencies.	Funded by individual patients and their health plans.
Timeframe	Depends on research protocols.	Requires real-time decisions.
Consent	Requires written informed consent.	May or may not require informed consent.
Assessment	Involves periodic and systematic assessment of patient data.	Based on as-needed patient assessment.
Protections	Protected by government agencies, institutional review boards, professional standards, informed consent, and legal standards.	Guided by state boards of medical practice, professional standards, peer review, informed consent, and legal standards.
Certainty	Tests products and procedures of unproven benefit to the patient.	Uses products and procedures accepted by the medical community as safe and effective.
Access to Information	Considered confidential intellectual property.	Available to the general public through product labeling.
Release of Findings	Published in medical journals, after clinical research ends.	Individual medical records are not released to the general public.

This FDA guidance provides a robust framework for distinguishing treatment from research.⁵⁰ Nevertheless, important questions remain at the margins.

⁴⁸ *Id.*

⁴⁹ *Clinical Research Versus Medical Treatment*, U.S. FOOD & DRUG ADMIN. (Feb. 24, 2016), <http://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/default.htm>.

⁵⁰ *Id.*

For example, the FDA guidelines do not indicate that medical treatment must be FDA-approved.⁵¹ The guidelines also fail to identify how to deal with cases where, with respect to a given medical intervention, some of the ten categories fall on the side of treatment, while others are more in line with research.⁵² Moreover, it is not clear whether each category is weighted equally, or if the answers to certain categories are determinative of whether an intervention is properly characterized as treatment or research.

Although deriving a bright-line rule to distinguish research from treatment may be a fruitless endeavor, identifying whether a particular medical intervention constitutes research or treatment is important for a variety of reasons. These reasons include: (1) providing the patient or research participant with accurate information as to the purpose and goals of the underlying medical intervention; (2) determining who should pay for the intervention; and (3) identifying which laws and regulations apply.

As to the legal and regulatory regimes, the framework governing medical treatment includes (1) state medical boards (which are responsible for licensing and disciplining providers and health care professionals), (2) professional standards of care (established by peer review and expert opinions, and reviewed by courts), and (3) legal doctrines such as informed consent.⁵³ Research is generally governed by the Common Rule and the Subparts of 45 C.F.R. Part 46,⁵⁴ though

⁵¹ *See id.*

⁵² *See id.*

⁵³ *See, e.g.,* B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPEDICS RELATED RES. 339 (2009); *Clinical Research Versus Medical Treatment*, U.S. FOOD & DRUG ADMIN. (Feb. 24, 2016), <http://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/default.htm>. Please note that the three examples provided in the text do not represent an exhaustive list of laws and regulations governing the practice of medicine.

⁵⁴ Many institutions voluntarily adopt the Common Rule requirements for all research involving human subjects even though the federal requirements only mandate that, for non-government-funded research, the institution commit to complying with general principles of human subjects research as, for instance, outlined in the Belmont Report. *See* 45 C.F.R. § 46 (2015); *see also* CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS (2015). For further reading on the Ebola example, *see* Timothy M. Uyeki et al., *Clinical Management of Ebola Virus Disease in the United States and Europe*, 374 NEW ENG. J. MED. 636 (2016).

FDA guidelines also apply if the research is related to a product under review by the FDA.⁵⁵

In cases where a medical intervention involves both research and treatment (e.g., access to a non-FDA approved drug to treat a patient with Ebola, where the results will be used to contribute to generalizable knowledge), protocols governing both research and treatment are implicated, and the law places the burden on the participating physicians, institutions, and/or researchers to implement the relevant procedures and protections.⁵⁶

B. Defining Vulnerability

For decades, protecting vulnerable populations has been a cornerstone of federal guidelines governing research with human subjects.⁵⁷ According to Carl Coleman, a leading scholar on the ethics and regulation of human subjects research, “despite the frequency with which the term vulnerability is used, little consensus exists on what it actually means in the context of human subject protection—or, more importantly, on how a finding of vulnerability should affect the process of research ethics review.”⁵⁸

The Belmont Report notes that “not every human being is capable of self-determination,” and further states that, because the capacity for self-determination may be compromised due to “illness, mental disability, or circumstances that severely restrict liberty,” some individuals “are in need of extensive protection.”⁵⁹ The Belmont Report also highlights that, throughout history, the benefits and burdens of research have not been fairly distributed.⁶⁰ This notion is particularly relevant to the selection of research subjects:

⁵⁵ See, e.g., *Regulations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulations> (last updated June 7, 2016).

⁵⁶ See, e.g., *id.*

⁵⁷ See Kathy L. Hudson & Francis S. Collins, *Bringing the Common Rule into the 21st Century*, 373 *NEW ENG. J. MED.* 2293, 2293 (2015).

⁵⁸ Coleman, *supra* note 1, at 12.

⁵⁹ The Belmont Report, *supra* note 38.

⁶⁰ *Id.* at 9–10.

[T]he selection of research subjects needs to be scrutinized in order to determine whether some classes (*e.g.*, welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.⁶¹

In such circumstances, the Belmont Report indicates that special considerations should be afforded to “[c]ertain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized.”⁶² While highly influential, the Belmont Report is not a legally binding document.⁶³ Notwithstanding, the report serves as persuasive authority because it is the ethical framework that spawned a thirteen-year process of detailed deliberation and agency rule-making, culminating with the enactment of the Common Rule in 1991.⁶⁴

Although the concept of vulnerability is a significant component of the ethics and regulation of research with human subjects, the Common Rule does not specifically define the term “vulnerable” in its list of Definitions.⁶⁵ Rather, in 45 C.F.R. § 46.107(a), the regulations note that vulnerable populations include groups “such as children, prisoners, pregnant women, or handicapped or mentally disabled persons,”⁶⁶ while in 45 C.F.R. § 46.111 the regulations define vulnerable populations to include groups “such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”⁶⁷

Though it is not clear why there is a discrepancy within the Common Rule, it may be due to an inadvertent oversight in drafting. Indeed, in the NPRM published on September 8, 2015, OHRP and HHS proposed to eliminate the discrepancy by amending both sections

⁶¹ *Id.*

⁶² *Id.* at 19.

⁶³ 45 CFR 46 FAQs, U.S. DEP’T OF HEALTH & HUMAN SERVS., www.hhs.gov/ohrp/humansubjects/guidance/ (last visited Mar. 25, 2016).

⁶⁴ *Id.*

⁶⁵ 45 C.F.R. § 46.102 (2015).

⁶⁶ *Id.* § 46.107(a).

⁶⁷ *Id.* § 46.111.

46.107(a) and 46.111 of the Common Rule to indicate that vulnerable populations include groups “such as children, prisoners, pregnant women, physically or mentally disabled persons, or economically or educationally disadvantaged persons.”⁶⁸ By using the words “such as,” both the Common Rule and the NPRM strongly suggest that the identified groups are not the sole groups that may be deemed vulnerable for purpose of the federal guidelines. At the same time, the identification of these five groups signals to IRBs the importance of closely scrutinizing protocols governing a research study that involves individuals from the groups.

The Common Rule dictates that IRBs must ensure that research protocols provide additional protections for studies that may include individuals from vulnerable populations.⁶⁹ For example, 45 C.F.R. § 46.107(a) states that, “if an IRB regularly reviews research that involves a vulnerable category of subjects,” that IRB should consider including “one or more individuals who are knowledgeable about and experienced in working with these subjects.”⁷⁰ Additionally, under 45 C.F.R. § 46.111(a)(3), the Common Rule states that, in determining whether the selection of research participants is equitable, IRBs “should be particularly cognizant of the special problems of research involving vulnerable populations.”⁷¹ And, in 45 C.F.R. § 46.111(b), the Common Rule provides that, as a condition of approval, IRBs must ensure that “[w]hen some or all of the subjects are likely to be vulnerable to coercion or undue influence . . . additional safeguards have been included in the study to protect the rights and welfare of these subjects.”⁷²

Coupled with the additional protections for vulnerable populations as outlined in the Common Rule, Subparts B, C, and D codify detailed requirements for research that includes pregnant

⁶⁸ NPRM, *supra* note 22, at 54,050–51.

⁶⁹ Some scholars have criticized the Common Rule for not providing sufficient guidance on how to conduct research that includes individuals from vulnerable populations. *See, e.g.,* Coleman, *supra* note 1, at 12.

⁷⁰ 45 C.F.R. § 46.107(a).

⁷¹ *Id.* § 46.111(a)(3).

⁷² *Id.* § 46.111(b).

women, children, human fetuses, neonates, and prisoners.⁷³ The need for the Subparts highlights a limitation of the Common Rule—specifically, that it does not provide adequate guidance as to what additional protections are needed for vulnerable populations. The supplemental protections, outlined in Subparts B, C, and D, include procedural guidelines addressing membership of IRBs that review research protocols involving vulnerable populations, as well as substantive guidelines that IRBs must consider in reviewing and monitoring the research.⁷⁴ For example, in a study involving prisoners, at least one prisoner or prisoner representative must be on the IRB, and a majority of the IRB (excluding any prisoners on the IRB) cannot be associated with the prison.⁷⁵ Additionally, the risks to prisoners must be commensurate with risks in studies not including prisoners, the decision to participate in research must not affect parole decisions, and the selection of prisoners must be free from coercion, undue influence, or arbitrary interventions by prison staff or other prisoners.⁷⁶

U.S. guidelines have opted to define vulnerability by categories of individuals, though “the diversity of the examples makes it difficult to identify what characteristics a group must have to be considered vulnerable.”⁷⁷ The group-based classifications have been criticized by many, including President Bill Clinton’s National Bioethics Advisory Commission, which noted that vulnerability “is sensitive to context, and individuals may be vulnerable in one situation but not in another.”⁷⁸ Carl Coleman argues that vulnerability should be conceptualized in three distinct forms—“consent-based, risk-based, and justice-based”—the first two require individualized calculations on specific people in certain situations, while the third necessitates a

⁷³ *Id.* §§ 46.201–46.409. The federal guidelines do not contain specific Subparts for other vulnerable populations, namely (1) physically or mentally disabled persons and (2) economically or educationally disadvantaged persons.

⁷⁴ *Id.* §§ 46.201–46.505.

⁷⁵ *Id.* §§ 46.301–46.304.

⁷⁶ *Id.* §§ 46.301–46.306.

⁷⁷ Coleman, *supra* note 1, at 12.

⁷⁸ NAT’L BIOETHICS ADVISORY COMM’N, *Ethical and Policy Issues in Research Involving Human Participants*, in REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 87 (Aug. 2001).

group-based analysis.⁷⁹ Carol Levine and colleagues point to “the possibility of physical harm” as the key component of vulnerability; that is, a vulnerable human subject is someone subject to “a heightened risk of injury.”⁸⁰ Samia Hurst takes this notion one step further and argues that vulnerability in research means being at a heightened risk of “a wrong,” which includes physical harm or other improprieties, such as not “getting fair consideration in resource allocation.”⁸¹ Frank Leavitt also takes a more expansive view than Levine, et al., and links vulnerability in research to circumstances where an individual is open to “an assault” on their “respect, health, or rights.”⁸²

The National Research Council (“NRC”), in an influential 2014 report commissioned by HHS after the agency issued the ANPRM, went as far as to recommend eliminating the vulnerable population language in the Common Rule, and suggested that HHS instead issue guidance “(a) distinguishing between vulnerabilities in participants’ lives and their vulnerability to research risks and (b) [on] procedures for assessing the extent to which the fit between participant characteristics and research procedures adequately minimizes research harms and discomforts.”⁸³ Specifically, the NRC called for distinguishing “social vulnerability from research vulnerability,” which means identifying “harm that may be caused by the research participation itself and harms that may be caused by the life situation or characteristics of the research participants.”⁸⁴

⁷⁹ Coleman, *supra* note 1, at 17.

⁸⁰ Levine et al., *supra* note 44, at 44–49.

⁸¹ Samia Hurst, *Vulnerability in Research and Health Care: Describing the Elephant in the Room*, 22 *BIOETHICS* 191, 191–202 (2008).

⁸² Frank Leavitt, *Is Any Research Population Not Vulnerable?*, 15 *CAMBRIDGE Q. HEALTHCARE ETHICS* 81, 81–88 (2006).

⁸³ NAT’L RESEARCH COUNCIL ET AL., PROPOSED REVISIONS TO THE COMMON RULE FOR THE PROTECTION OF HUMAN SUBJECTS IN THE BEHAVIORAL AND SOCIAL SCIENCES 68 (2014) [hereinafter NRC Report].

⁸⁴ See *id.* at 67. While the NRC’s recommendations were set forth in a report that focused on research in the social and behavioral sciences, the NRC did not limit its recommendations solely to social and behavioral science research, and there is nothing in the report that suggests that the NRC’s rationale underlying social and research vulnerability differs in other research settings. See *id.* at 74–75.

Despite OHRP and HHS acknowledging that the agencies benefited from the NRC's suggestions,⁸⁵ the NPRM does not eliminate the group-based approach to defining vulnerability. To the contrary, the NPRM clarifies the discrepancy between 45 C.F.R. § 46.107(a) and 45 C.F.R. § 46.111 (highlighted at the beginning of this Subsection),⁸⁶ and notes that OHRP and HHS intend to suggest revisions to the Subparts of 45 C.F.R. § 46 that deal with vulnerable populations.⁸⁷ In short, while a group-based approach to defining vulnerability has its limitations—for example, it assumes that all individuals within a given group have equal burdens, benefits, fears, needs, etc.—a categorical framework is likely to be an integral component of the Common Rule for the foreseeable future.

II. MARKERS OF VULNERABILITY FOR SERVICE MEMBERS⁸⁸

In many respects, military medicine and research are no different than civilian medicine and research. Military doctors conduct examinations to assess health, administer vaccinations for individual and public health goals, and provide treatment for acute and chronic conditions.⁸⁹ Military clinical researchers must seek and obtain IRB approval for their work and are bound by FDA guidelines for medical products under review by the agency.⁹⁰ As in non-military settings, military physicians and researchers have fiduciary duties and are obligated to follow accepted standards of care and regulatory protocols.⁹¹

⁸⁵ NPRM, *supra* note 22, at 53,939.

⁸⁶ *Id.* at 54,050–51.

⁸⁷ *Id.* at 53,942.

⁸⁸ Portions of Subsections A, B, C, and F are adapted from Efthimios Parasidis, *Emerging Military Technologies: Balancing Medical Ethics and National Security*, 47 CASE W. RES. J. INT'L L. 167 (2015) and Parasidis, *supra* note 11.

⁸⁹ See generally Edmund G. Howe, *Ethical Issues Regarding Mixed Agency of Military Physicians*, 23 SOC. SCI. MED. 803 (1986) (describing military physicians' competing obligations, particularly during combat).

⁹⁰ 45 C.F.R. §§ 46.111, 46.102(e) (2015).

⁹¹ See generally DEF. HEALTH BD., U.S. DEP'T OF DEF., *ETHICAL GUIDELINES AND PRACTICES FOR U.S. MILITARY MEDICAL PROFESSIONALS* (2015) (describing and evaluating the U.S. military's medical professional practices, policies, and guidelines).

Despite the similarities, there are significant areas of divergence. When placed into context, these areas of divergence represent markers of vulnerability for service members. They include: (1) military command structure; (2) a nebulous boundary between treatment and research in military settings; (3) informed consent waivers for military personnel; (4) military culture; (5) the predominance of force health priorities over individual health concerns; and (6) governmental immunities and limitations on tort claims by service members.

A. Military Command Structure

Command structure is embedded in all aspects of the military, and military medicine is no exception.⁹² Under the Uniform Code of Military Justice (“UCMJ”), the legal system governing the armed forces, a subordinate officer must obey a lawful order of a superior officer.⁹³ This provision applies in equal force if the order is a split-second, combat-related command given on the battlefield, or an order given on a U.S. base that relates to a medical treatment deemed by officials to be necessary for the good of the armed forces.⁹⁴

With respect to the latter, existing regulations do not limit medical-related orders to products approved by the FDA.⁹⁵ And, on a number of occasions, the DoD has mandated that soldiers submit to non-FDA-approved medical products as a requirement of service.⁹⁶

⁹² See *Introduction to the U.S. Army Medical Department*, ARMY MED., <http://armymedicine.mil/Pages/Introduction-to-the-US-Army-Medical-Department.aspx> (July 5, 2016).

⁹³ *United States v. Washington*, 57 M.J. 394, 396 (C.A.A.F. 2002).

⁹⁴ *Id.* at 398. Notably, it was not until 1981 that DoD guidelines were amended to prohibit penalties from being imposed on service members who refused to volunteer for (or who withdrew from) military research. See Maxwell J. Mehlman & Stephanie Corley, *A Framework for Military Bioethics*, 13 J. MIL. ETHICS 331, 343 (2014) (citing Arthur Anderson, *A Brief History of Military Contributions to Ethical Standards for Research Involving Human Subjects*).

⁹⁵ See *Determination that Informed Consent is Not Feasible or Is Contrary to the Best Interests of the Recipients*, 64 Fed. Reg. 54,180 (Oct. 5, 1999) (to be codified at 21 C.F.R. pts. 50, 312); *Waiving Informed Consent: Military Use of Non-FDA-Approved Drugs in Combat*, RAND CORP., http://www.rand.org/pubs/research_briefs/RB7534/index1.html (last visited May 15, 2016).

⁹⁶ See U.S. DEP’T OF DEF., INSTR. 6200.02, APPLICATION OF FOOD AND DRUG ADMINISTRATION (FDA) RULES OF DEPARTMENT OF DEFENSE FORCE HEALTH PROTECTION PROGRAMS (2008) [hereinafter DoD Instruction 6200.02] (stipulating, *inter alia*, considerations upon Heads of DoD Components when deciding whether to order vaccination of military forces using non-

Under the UCMJ, refusal to submit equates to disobeying an order and can result in punitive measures, including reduction in rank, docked pay, jail time, and a dishonorable discharge.⁹⁷

Sanctions pursuant to this provision are not merely theoretical. Since the 1990s, the DoD has prosecuted hundreds of service members, including military physicians who have refused administration of medical products that were not approved by the FDA for the use intended by the DoD.⁹⁸ During the prosecutions, military courts consistently denied requests by soldiers to submit evidence of safety concerns, holding that such information was irrelevant to the underlying issue of whether the soldier disobeyed a lawful command.⁹⁹

When compared to medical treatment deemed to be a requirement of service, the rigors of military command structure are less present in clinical research conducted or sponsored by the military. As discussed, the DoD has adopted the Common Rule,¹⁰⁰ and Executive Order 12333 mandates that the CIA comply with the Common Rule's guidelines.¹⁰¹ In addition, DoD policies provide additional safeguards for service members who are solicited for, or enrolled in, clinical trials that are conducted or sponsored by the government.¹⁰²

FDA-approved medicines).

⁹⁷ See *Washington*, 57 M.J. at 396 (noting that Airman Washington's refusal to be inoculated with an anthrax vaccine was properly regarded as insubordination by his superior officer and the Air Force court martial).

⁹⁸ Randall D. Katz, *Friendly Fire: The Mandatory Military Anthrax Vaccination Program*, 50 DUKE L.J. 1835, 1837, 1853, 1863 (2001).

⁹⁹ See, e.g., *Bates v. Rumsfeld*, 271 F. Supp. 2d 54, 64 (D.D.C. 2004); see *Washington*, 57 M.J. at 398-99.

¹⁰⁰ Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003, 28,012 (June 18, 1991) (to be codified at 32 C.F.R. pt. 219).

¹⁰¹ Exec. Order No. 12,333, 46 Fed. Reg. 59,941, § 2.10 (Dec. 4, 1981) ("No element of the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines.").

¹⁰² See, e.g., U.S. DEP'T OF DEF., INSTR. 3216.02, PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DOD-SUPPORTED RESEARCH (2011) [hereinafter DoD Instruction 3216.02], <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

These additional protections include a requirement that commanding officers not be present during solicitation of research participants, the use of an ombudsman for group briefings with active duty personnel, and the appointment of medical monitors for research involving greater than minimal risk to research participants.¹⁰³ At the same time, however, there are exceptions that negate many of the additional protections in certain circumstances—notably, the informed consent waiver, which is discussed, *infra*, in Subsection C. Furthermore, since the boundary between research and treatment is particularly amorphous in military settings, the circumstances in which the research-related protections actually apply are limited.

B. A Nebulous Boundary Between Treatment and Research for Military Personnel

For military personnel, the line between research and treatment is particularly vague. DoD Instruction 3216.02 defines a key triggering term for Common Rule protections—“research involving human subjects”—to exclude “[a]ctivities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs[.]”¹⁰⁴ Under this provision, use of non-FDA-approved products, or off-label use of an FDA-approved product, is permitted so long as the reason for the use is treatment-related, rather than research-related.¹⁰⁵

Thus, rather than focusing on the underlying medical product—and whether the product (1) is FDA-approved, (2) constitutes an accepted standard of care, or (3) has a reasonable expectation of conferring a benefit to the recipient—DoD Instruction 3216.02 shifts the inquiry to the rationale underlying the use of the medical product.¹⁰⁶ Namely, the question becomes whether military officials

¹⁰³ See GUIDELINES FOR INVESTIGATORS: REQUIREMENTS FOR U.S. ARMY MEDICAL RESEARCH AND MATERIAL COMMAND (USAMRMC) HEADQUARTERS REVIEW AND APPROVAL OF RESEARCH INVOLVING HUMAN VOLUNTEERS, HUMAN ANATOMICAL SUBSTANCES, AND/OR HUMAN DATA 14-15 (2007).

¹⁰⁴ DoD Instruction 3216.02, *supra* note 102, Glossary, at 37.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

have indicated that the medical product is being used for research, or for the “diagnosis, treatment or prevention of injury and disease.”¹⁰⁷

A separate DoD guidance document underscores this line of reasoning, stating that research includes “an intervention or interaction with a human being for the *primary purpose* of obtaining data regarding the effect of the intervention or interaction.”¹⁰⁸ Thus, so long as the military casts the primary purpose of a medical intervention as treatment-related, research protocols will be inapplicable. Importantly, under the UCMJ, military personnel are legally required to submit to “treatment” with such medical products.¹⁰⁹

Pursuant to DoD Instruction 3216.02, activities related to an “operational test and evaluation” (“OT&E”) project are excluded from the definition of “research involving human subjects.”¹¹⁰ Under 10 U.S.C. § 139, an OT&E project is a “field test, under realistic combat conditions, of any item (or key component of) weapons, equipment, or munitions for the purpose of determining the effectiveness and suitability of the weapons, equipment, or munitions for use in combat by typical military users.”¹¹¹ Field-testing “may often be hazardous, may involve the use of volunteers, but may not be considered human research.”¹¹² Under such circumstances, regulations governing research with human subjects do not apply.¹¹³

It is unclear whether the definition of OT&E projects includes medical products, though there is nothing that affirmatively states that medical products are excluded.¹¹⁴ Moreover, the terms “weapons” or “equipment” arguably would include medical devices that are

¹⁰⁷ *Id.*

¹⁰⁸ U.S. DEP'T OF DEF., DoD AND OUSD(P&R) SPECIFIC AND UNIQUE REQUIREMENTS, § 3.2.0 (titled, “DoD Directive 3216.02 clarification of 10 USC 980”) (emphasis added).

¹⁰⁹ *United States v. Washington*, 57 M.J. 394, 396 (C.A.A.F. 2002).

¹¹⁰ DoD Instruction 3216.02, *supra* note 102, at 37.

¹¹¹ 10 U.S.C. § 139 (2012).

¹¹² U.S. ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT 485 (1995).

¹¹³ *See id.*; *see also* Memorandum from John A. Casciotti, Assoc. Deputy Gen. Counsel (Health Affairs), to the Dir. of Biological Systems, Off. of the Dir. of Def. Research & Engineering, Dep't of Def. 3 (Oct. 22, 2004).

¹¹⁴ *See* 10 U.S.C. § 139.

combat-related, such as brain-to-computer interfaces.¹¹⁵ The DoD and DARPA have been researching brain-to-computer interfaces for years, including interfaces that utilize novel techniques such as transcranial direct current stimulation, transcranial magnetic stimulation, transcranial pulsed ultrasound stimulation, and deep brain stimulation via implanted electrodes.¹¹⁶ Part of the goal in researching these interfaces is to create “smart” equipment that can be linked to the thoughts of a person.¹¹⁷ At the same time, studies have raised serious questions as to short- and long-term adverse health consequences from such devices.¹¹⁸

The blurring of research and treatment for military personnel is not only derived from DoD guidelines, it is embedded in the post-9/11 national security legal framework—for example, in the Project BioShield Act of 2004. Among its provisions, the BioShield Act created the Emergency Use Authorization (“EUA”) process, which provides the FDA with the authority to grant permission to use a medical product for off-label or investigational purposes during a declared

¹¹⁵ For example, in the context of accounting policy, the DoD defines “military equipment” broadly to include “all weapons systems, weapons platforms, vehicles, and munitions of the Department of Defense, and the components of such items.” See Military Equipment Definition, Memorandum from Nancy L. Spruill, Dir. of Acquisition Res. & Analysis, to Assistant Secretary of the Army et al. 3 (Jan. 24, 2007), http://www.acq.osd.mil/pepolicy/pdfs/reference_library/ME%20Definition.pdf. Moreover, “weapons systems” are defined as “items that can be used directly by the Armed Forces to carry out combat missions.” *Id.*

¹¹⁶ See, e.g., Roy Hamilton et al., *Rethinking the Thinking Cap*, 76 *NEUROLOGY* 187 (2011); Roi Cohen Kadosh et al., *The Neuroethics of Non-Invasive Brain Stimulation*, 22 *CURRENT BIOLOGY* R108 (2012); Jan-Hendrik Heinrichs, *The Promises and Perils of Non-Invasive Brain Stimulation*, 35 *INT. J.L. & PSYCHIATRY* 121 (2012); Bjorn Schmitz-Luhn et al., *Law and Ethics of Deep Brain Stimulation*, 35 *INT. J.L. & PSYCHIATRY* 130 (2012); Jean Levasseur-Moreau et al., *Non-Invasive Brain Stimulation Can Induce Paradoxical Facilitation: Are These Neuroenhancements Transferable and Meaningful to Security Services?*, 7 *FRONTIERS HUMAN NEUROSCIENCE* 1 (2013); Bernard Sehm & Patrick Ragert, *Why Non-Invasive Brain Stimulation Should Not be Used in Military and Security Services*, 7 *FRONTIERS HUMAN NEUROSCIENCE* 1 (2013); Jerome Brunelin et al., *Is it Ethical and Safe to Use Non-Invasive Brain Stimulation as a Cognitive and Motor Enhancer Device for Military Services?: A Reply to Sehm and Ragert (2013)*, 7 *FRONTIERS HUMAN NEUROSCIENCE* 1 (2013).

¹¹⁷ See, e.g., Michael N. Tannison & Jonathan D. Moreno, *Neuroscience, Ethics, and National Security: The State of the Art*, 10 *PLOS BIOLOGY* 1, 1 (2012); see also JONATHAN D. MORENO, *MIND WARS: BRAIN RESEARCH AND NATIONAL DEFENSE* 4 (2006); Hannah Hoag, *Remote Control*, 423 *NATURE* 796, 796 (2003).

¹¹⁸ See, e.g., Heinrichs, *supra* note 116, at 121; Schmitz-Luhn et al., *supra* note 116, 130; Sehm & Ragert, *supra* note 116, at 1; Brunelin et al., *supra* 116, at 1.

emergency.¹¹⁹ Although an EUA may be issued for both civilian and military populations, only military personnel are subject to forced use.¹²⁰

For example, assume that researchers are working on a next generation anthrax vaccine, and that the new vaccine has yet to earn FDA approval. If U.S. service members are called into a combat area and there is evidence that one of the belligerents has engineered a new form of anthrax that the existing anthrax vaccine is powerless against, the DoD can obtain an EUA under the BioShield Act to require that service members be inoculated with the non-FDA approved anthrax vaccine. Should this new strain of anthrax be used against U.S. troops, the DoD and vaccine manufacturer can then study the effectiveness of the experimental vaccine. Since the primary purpose underlying the use is troop protection, not research, the DoD can mandate inoculation with the investigational vaccine, and the informed consent of service members is not required.¹²¹

C. Informed Consent Waivers

Coupled with the provisions of the BioShield Act, informed consent waivers are permitted when military officials deem a medical product to be a requirement of service.¹²² In such circumstances, the President of the United States is authorized to issue an informed consent waiver, so long as the use is “in connection with the member’s participation in a particular military operation.”¹²³ This power was previously in the hands of the FDA via an interim final regulation issued by the agency, but the FDA rescinded its own interim final rule following a controversy surrounding the FDA’s issuance of a waiver during the Gulf War in the early 1990s.¹²⁴ The circumstances

¹¹⁹ See Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004); see also DoD Instruction 6200.02, *supra* note 96 (describing various procedures for obtaining an EUA).

¹²⁰ 21 U.S.C. § 360bbb-3 (2012).

¹²¹ See 21 U.S.C. §§ 360bbb-3(j)(1)–(2) (2012) (indicating that an informed consent waiver may be issued for members of the armed forces).

¹²² 10 U.S.C. § 1107(f) (2012).

¹²³ *Id.*

¹²⁴ See Stuart L. Nightingale et al., *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13 EMERGING INFECTIOUS DISEASES

surrounding the issuance of the Gulf War informed consent waiver merit close examination.

In the midst of the Iran-Iraq War (1980–1988), Iraq deployed chemical weapons against Iran.¹²⁵ The U.S. government supported Iraq during the war, though, as the late Jonathan Tucker explained, the United States kept “its support low-profile.”¹²⁶ In addition, companies from the United States, France, West Germany, the Netherlands, and Switzerland provided Iraq with chemicals and specialized equipment that Iraq utilized to build its chemical weapons arsenal.¹²⁷ Iran repeatedly pleaded for assistance from the international community, and inspectors from the United Nations later confirmed that Iraq had used tabun, mustard gas, and other toxic substances against Iranian soldiers and civilians.¹²⁸ In the end, the international community did not take any meaningful steps to punish Iraq for its use of chemical weapons.¹²⁹

In 1990, two years after the conclusion of the Iran-Iraq War, Iraq invaded neighboring Kuwait.¹³⁰ Shortly thereafter, the United States intervened on the side of Kuwait, cognizant of the very real possibility that Iraq might use chemical or biological weapons against U.S. service members.¹³¹ For example, the CIA estimated that Iraq had over 1,000 tons of chemical weapons that were loaded into various munitions.¹³² Medically, there was little the military could do to protect U.S. troops,

1046, 1047 (2007).

¹²⁵ See JONATHAN B. TUCKER, *WAR OF NERVES: CHEMICAL WARFARE FROM WORLD WAR I TO AL-QAEDA* 250–53 (Pantheon Books 2006).

¹²⁶ See *id.* at 252. Mr. Tucker was a well-respected chemical and biological weapons specialist, and held a position at the Center for Nonproliferation Studies at the Monterey Institute of International Studies.

¹²⁷ See *id.* at 250–53.

¹²⁸ See *id.* at 258–59. In response to Iraq’s use of chemical weapons, Iran began its own chemical weapons program (the country did not have chemical weapons at the start of the war) by also purchasing key materials from Western companies. See *id.*

¹²⁹ See, e.g., Javed Ali, *Chemical Weapons in the Iran-Iraq War: A Case Study in Noncompliance*, 8.1 *NONPROLIFERATION REV.* 43, 43 (2001).

¹³⁰ *Id.* at 55.

¹³¹ *Id.* at 52; JUDITH MILLER ET AL., *GERMS: BIOLOGICAL WEAPONS AND AMERICA’S SECRET WAR 88–89* (2002).

¹³² See Tucker, *supra* note 125, at 304.

since there were no FDA-approved products that protected against the chemical or biological threats.¹³³

With this as a backdrop, the DoD mandated that, prior to deployment, service members be “pretreated” with pyridostigmine bromide (PB) and the botulinum toxoid (BT) vaccine as prophylaxis for anticipated chemical and biological warfare.¹³⁴ At the time, neither product was being studied in a clinical trial or other study, though previously the BT vaccine was manufactured and used by the U.S. Centers for Disease Control and Prevention (“CDC”) pursuant to an investigational new drug waiver from the FDA.¹³⁵

Although the military was interested in learning whether the products actually protected against chemical and biological weapons, the military indicated that its primary motivation was troop protection, so administration of the medical products was not considered research.¹³⁶ Nevertheless, because the products were investigational (i.e., not approved by the FDA as prophylaxis for chemical or biological warfare), regulations required that the DoD obtain informed consent from service members prior to use.¹³⁷ Upon request from the DoD, the FDA waived the informed consent requirement.¹³⁸

Following the war, veterans began suffering from serious health problems that included cognitive difficulties, chronic headaches, musculoskeletal problems, respiratory ailments, and widespread pain, and had children born with birth defects at an alarming rate.¹³⁹ In 2008,

¹³³ See Ali, *supra* note 129, at 46–47; MILLER ET AL., *supra* note 131, at 88–89.

¹³⁴ Doe v. Sullivan, 938 F.2d 1370, 1372 n.1 (D.C. Cir. 1991). PB was approved by the FDA in the 1950s as a treatment for myasthenia gravis, a rare neuromuscular disease that leads to muscle weakness. *See id.*

¹³⁵ See Mehlman & Corley, *supra* note 94, at 341. Despite the fact that it had yet to earn FDA approval, the BT vaccine had been used for over twenty years as a preventive measure for individuals at risk of occupational exposure to botulism. *See Sullivan*, 938 F.2d at 1372 n.1.

¹³⁶ *See Mehlman & Corley*, *supra* note 94, at 341.

¹³⁷ Determination That Informed Consent is Not Feasible, 55 Fed. Reg. 52,814, 52,814 (Dec. 21, 1990) (codified at 21 C.F.R. § 50 (2015)).

¹³⁸ *See* RICHARD A. RETTIG, MILITARY USE OF DRUGS NOT YET APPROVED BY THE FDA FOR CW/BW DEFENSE 7 (1999).

¹³⁹ *See* RESEARCH ADVISORY COMM. ON GULF WAR VETERANS' ILLNESSES, GULF WAR ILLNESS & THE HEALTH OF GULF WAR VETERANS: SCIENTIFIC FINDINGS AND RECOMMENDATIONS (2008)

nearly two decades after administration of the experimental products, studies revealed that PB was one of the factors that most likely caused the health problems.¹⁴⁰ Commonly referred to as Gulf War Illness, the symptoms have affected between 175,000 and 250,000 veterans, which equates to approximately one-third of the fighting force during the war.¹⁴¹

The complete details surrounding the controversy between the FDA and the DoD are not publicly known. Of the information that is in the public domain, it is clear that the FDA believed that the DoD was not being forthright in its negotiations with the FDA. The FDA claims that it granted the waiver because it believed that the DoD determined that military necessity required an informed consent waiver for investigational use of unapproved products.¹⁴² On the other hand, the DoD claims that it believed the FDA had granted permission to use the products without informed consent because the FDA believed that the products were safe.¹⁴³

Regardless of why the waiver was granted, as a condition of FDA permission to use investigational products without informed consent, the DoD agreed to: (1) provide information on PB to all service members; (2) collect, review, and make reports of adverse events related to PB; (3) label PB as an investigational product that was solely for “military use and evaluation”; (4) ensure that each dose of the BT vaccine was recorded in each service member’s medical record; and (5) maintain adequate records related to the receipt, shipment, and disposition of the BT vaccine.¹⁴⁴ The DoD failed to comply with each of these requirements.¹⁴⁵

[hereinafter GULF WAR ILLNESS REPORT].

¹⁴⁰ *Id.*; see also *Justice Delayed: Acknowledging the Reality of Gulf War Illness*, 372 LANCET 1856 (2008). Other potential factors include oil well fires, demolished chemical or biological weapons, depleted uranium, pesticides, and chemical agent resisting paint. See *Gulf War Exposures*, U.S. DEP’T OF VETERANS AFFAIRS, <http://www.publichealth.va.gov/exposures/gulfwar/sources/index.asp> (last visited July 11, 2016).

¹⁴¹ GULF WAR ILLNESS REPORT, *supra* note 139, at 4.

¹⁴² Annas & Annas, *supra* note 17, at 302.

¹⁴³ *Id.* at 301-02.

¹⁴⁴ Revocation of 1990 Interim Final Rule, 64 Fed. Reg. 54,180, 54,184 (Oct. 5, 1999).

¹⁴⁵ See *id.*

Following this debacle and a series of discussions and proposed rules, Congress enacted 10 U.S.C. § 1107(f), discussed at the beginning of this Subsection, which grants the President the power to issue an informed consent waiver.¹⁴⁶ Section 1107(f) became effective on October 17, 1998.¹⁴⁷ Less than a year later, the FDA revoked its own interim final rule that provided the agency with the authority to issue informed consent waivers to the DoD.¹⁴⁸

A few months prior to the enactment of 10 U.S.C. § 1107(f), the DoD commenced mandatory inoculations with the anthrax vaccine pursuant to its Anthrax Vaccine Immunization Program (“AVIP”).¹⁴⁹ At the time, the anthrax vaccine was only approved by the FDA to protect against cutaneous anthrax, which is anthrax that comes into contact with the skin.¹⁵⁰ However, the DoD feared the potential use of airborne anthrax as a biological weapon.¹⁵¹ Many reports had identified countries—including Iraq—which maintained stockpiles of weapons-grade anthrax, and U.S. authorities estimated that additional nations or terrorist groups had begun to acquire the deadly pathogen too.¹⁵²

From the outset, the AVIP caused considerable controversy.¹⁵³ Congress criticized the program, dubbing it an “overwrought response to the threat of anthrax” and one that “compromises the practice of medicine to achieve military objectives.”¹⁵⁴ A Congressional

¹⁴⁶ 10 U.S.C. § 1107(f) (2012).

¹⁴⁷ Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, Pub. L. No. 105-261, § 1513, 112 Stat. 1920 (1998).

¹⁴⁸ *See id.*

¹⁴⁹ *Rempfer v. Sharfstein*, 583 F.3d 860, 863 (D.C. Cir. 2009).

¹⁵⁰ *See id.* at 863–67.

¹⁵¹ H.R. REP. NO. 106-556, at 5–9 (2000) [hereinafter ANTHRAX VACCINE CONGRESSIONAL REPORT].

¹⁵² *See id.*

¹⁵³ *Id.* at 2. Shortly after implementation of the AVIP, the military encountered a supply shortage that resulted in a temporary suspension of the program. Service members who had begun the six-dose schedule were forced to miss doses. When the military regained a supply of the vaccine, it indicated that those service members who began the dosing schedule would not repeat doses but would continue with the next dose of the vaccine. This was contrary to the label indication for the vaccine. *Rempfer*, 583 F.3d at 862–64.

¹⁵⁴ ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 151.

committee found that the DoD provided service members with “[h]eavy handed, one-sided informational materials[,]” that the agency was “far more concerned with public relations than effective force protection or the practice of medicine[,]” and that, pursuant to FDA regulations, use of the vaccine for inhalation anthrax amounted to investigational use.¹⁵⁵ The committee recommended that the program be halted until the DoD could obtain FDA approval to use the vaccine as a pretreatment for inhalation anthrax.¹⁵⁶

The DoD refused to suspend the AVIP, and within the first two years of the program no less than twenty-four service members were discharged “under other than honorable conditions” for refusing the anthrax vaccine.¹⁵⁷ By 2002, disciplinary action had been taken in well over 100 Air Force cases alone, including at least one Air Force physician who refused to be vaccinated.¹⁵⁸

The few publicly available military court decisions from the anthrax cases provide significant insight into the DoD’s legal justifications for mandating off-label use of the vaccine. DoD prosecutors repeatedly sought to exclude all evidence concerning the safety and efficacy of the anthrax vaccine, and military judges consistently granted these motions.¹⁵⁹ Service members argued that the off-label use of the vaccine amounted to investigational use under FDA requirements, but military courts staunchly upheld the AVIP,

¹⁵⁵ *Id.* at 2–3. According to the report, the DoD’s efforts fueled “suspicions the program understates adverse reaction risks in order to magnify the relative, admittedly marginal, benefits of the vaccine.” *Id.* at 2.

¹⁵⁶ *Id.* at 4.

¹⁵⁷ JONATHAN D. MORENO, *UNDUE RISK: SECRET STATE EXPERIMENTS ON HUMANS* 269 (2000). One of the discharged service members later stated:

[F]or you to believe the military would never do anything to hurt me, then I suggest you talk to the many sick Americans that returned from the Persian Gulf. I love this country and I am willing to die, but only in war. Not because they are experimenting on me.

Id.

¹⁵⁸ See *Bates v. Rumsfeld*, 271 F. Supp. 2d 54, 57–58 (D.D.C. 2004); *United States v. Washington*, 57 M.J. 394, 400 (C.A.A.F. 2002); Katz, *supra* note 98, at 1837.

¹⁵⁹ See, e.g., *United States v. Johnson*, No. NMCCA 200001433, 2004 WL 720153, at *1 (N-M. Ct. Crim. App. 2004); *Washington*, 57 M.J. at 396; *Perry v. Wesely*, No. NMCM 200001397, 2000 WL 1775249, at *1 (N-M. Ct. Crim. App. 2000); *Ponder v. Stone*, 54 M.J. 613, 614 (N-M. Ct. Crim. App. 2000).

citing military directives and instructions that characterized the anthrax vaccine as “an FDA-licensed product and not an IND requiring informed consent for its administration.”¹⁶⁰ These characterizations contradicted earlier positions taken by the agency wherein it “acknowledged tacitly” that use of the vaccine for inhalation anthrax constitutes investigational use.¹⁶¹

Despite a long line of losing efforts, service members continued to refuse the vaccine and challenge resulting military sanctions in court.¹⁶² In 2003, six service members filed a lawsuit seeking to enjoin the DoD from continuing the AVIP, since the agency did not obtain informed consent prior to inoculations, nor did it obtain a presidential waiver from the informed consent requirements.¹⁶³ A federal district court granted the injunction, finding that the AVIP amounted to off-label use of a vaccine and that the DoD failed to comply with one of the two options regarding informed consent: (1) obtain consent from each service member; or (2) have the President of the United States issue an informed consent waiver.¹⁶⁴

Eight days after the injunction, the FDA approved the anthrax vaccine “independent of the route of exposure,” which captured the indication of inhalation anthrax.¹⁶⁵ Upon further challenge by the service members, the court vacated the FDA’s decision on procedural grounds because the agency did not adhere to regulations governing approval of the new indication.¹⁶⁶ Notably, the court also rejected the DoD’s arguments that a soldier’s refusal to submit to the order to be

¹⁶⁰ *Ponder*, 54 M.J. at 616–17; *see also* *United States v. Schwartz*, 61 M.J. 567, 571 (N.M. Ct. Crim. App. 2005); *Perry*, 2000 WL 1775249, at *3. The cases reference various directives and instructions, as set forth by the DoD and as implemented by the various branches of the military. For example, Department of Navy Instruction 6230.4 (dated April 29, 1998) implements Department of Defense Directive 6205.3 (DoD Immunization Program for Biological Warfare Defense) and the Secretary of Defense’s December 15, 1997 order regarding mandatory anthrax immunizations. *See* DEP’T OF NAVY, INSTR. 6230.4, DEPARTMENT OF NAVY ANTHRAX VACCINATION IMPLEMENTATION PROGRAM (AVIP) (April 29, 1998).

¹⁶¹ *Katz*, *supra* note 98, at 1861.

¹⁶² *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 3 (D.D.C. 2004).

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 6.

¹⁶⁵ *Id.*

¹⁶⁶ *See id.* at 13–16.

inoculated with the anthrax vaccine would “undermine a key component of military readiness and defense” and that “requiring the DoD to obtain informed consent will interfere with the smooth functioning of the military.”¹⁶⁷

Thereafter, Congress stepped in to aid the DoD by enacting the Project BioShield Act of 2004.¹⁶⁸ This law was then used to grant the DoD the ability to continue using the anthrax vaccine for unapproved indications, a move that trumped the court order halting the AVIP.¹⁶⁹ During the time that the DoD was permitted to continue with the AVIP pursuant to the emergency order, the FDA approved the anthrax vaccine regardless of the route of exposure.¹⁷⁰ Although the service members again challenged the FDA’s decision, the U.S. Court of Appeals for the D.C. Circuit dismissed the action because it found that the FDA did not act arbitrarily or capriciously in approving the new indication during the second review.¹⁷¹ Since March 1998, over 2,300,000 service members have received the anthrax vaccine.¹⁷²

The informed consent waivers for PB, the BT vaccine, and the anthrax vaccine were provided in the context of medical treatment, not research, though the DoD gathered research-related information from the programs.¹⁷³ Thus, each example fell into a “gray area” where research and treatment overlap.

¹⁶⁷ Doe v. Rumsfeld, 297 F. Supp. 2d 119, 123, 134 (D.D.C. 2003). As the court indicated, “[A]bsent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.” *Id.* at 135.

¹⁶⁸ See *supra* text at note 119.

¹⁶⁹ See Nightingale et al., *supra* note 124, at 1046. During the pendency of the emergency order, the DoD administered more than 100,000 anthrax vaccinations. See *id.* at 1050.

¹⁷⁰ Rempfer v. Sharfstein, 583 F.3d 860, 864 (D.D.C. 2009).

¹⁷¹ *Id.* at 868.

¹⁷² See DEP’T OF DEF., HEALTHCARE PROVIDER’S BRIEFING: ANTHRAX VACCINE 20 (2009), https://www.vaccines.mil/documents/1279Anthrax%20HCP%20Brief%20-%2014%20Sep%2009_printable.pdf.

¹⁷³ By contrast, for example, a waiver is not required for FDA-approved vaccines, such as the smallpox vaccine or influenza vaccine. The DoD can make these treatments a requirement of service under the UCMJ. See *supra* Subsection III.A (discussing how the DoD can mandate that service members be compelled to take FDA-approved products); see, e.g., United States v. Washington, 57 M.J. 394, 398 (C.A.A.F. 2002).

For informed consent waivers in research settings, a complex web of federal regulations and DoD guidelines apply. The Common Rule allows for informed consent waivers in limited circumstances.¹⁷⁴ For example, under 45 C.F.R. § 46.116(c), an IRB can waive some or all of the informed consent requirements if the IRB determines that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.¹⁷⁵

Furthermore, though not specifically identified in the Common Rule, guidance from the FDA allows for informed consent waivers for “emergency research,” which encompasses situations where:

[H]uman subjects who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent. The research must have the prospect of direct benefit to the patient and must involve an investigational product that, to be effective, must be administered before informed consent from the subject or the subject’s legally authorized representative can be obtained and in which there is no reasonable way to identify prospectively individuals likely to become eligible for participation.¹⁷⁶

The informed consent waiver for emergency research does not exclude military personnel.¹⁷⁷

¹⁷⁴ 45 C.F.R. §§ 46.116, 46.117 (2015).

¹⁷⁵ *Id.* § 46.116(d). Under the Common Rule, an informed consent waiver is also available for certain research “conducted by or subject to the approval of state or local government officials” in the context of “public benefit or service programs[.]” but only if the research “could not practicably be carried out without the waiver or alteration.” *Id.* § 46.116(c).

¹⁷⁶ OFF. OF GOOD CLINICAL PRACTICE, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS, CLINICAL INVESTIGATORS, AND SPONSORS: EXCEPTION FROM INFORMED CONSENT REQUIREMENTS FOR EMERGENCY RESEARCH 1 (2011).

¹⁷⁷ *See id.*; 32 C.F.R. §§ 219.116(c)–(d) (2015); DoD Instruction 3216.02, *supra* note 102, § 9, at 25–

Moreover, military personnel are subject to additional circumstances in which a research-related informed consent waiver may apply. Under 10 U.S.C. § 980(b), the Secretary of Defense has the authority to issue an informed consent waiver if a project aims to “advance the development of a medical product necessary to the armed forces” and “may directly benefit the subject.”¹⁷⁸ Section 980(b) does not describe the procedure that must be employed when a research-related informed consent waiver is granted, nor does the law limit the type of research that may be conducted pursuant to the waiver.¹⁷⁹ That said, pursuant to DoD Instruction 3216.02, the informed consent waiver in Section 980(b) applies solely to “DoD funded research involving a human being as an experimental subject.”¹⁸⁰

As DoD Instruction 3216.02 makes clear, “[r]esearch involving a human being as an experimental subject is a subset of research involving human subjects.”¹⁸¹ Specifically, research involving a human being as an experimental subject includes “[a]n 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.”¹⁸² The broader category of research involving human subjects includes “[a]ctivities that include both a systematic investigation designed to develop or contribute to generalizable knowledge [and] involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.”¹⁸³ Importantly, as outlined, *supra*, in Subsection B, the broader category of research involving human subjects excludes, *inter alia*, “[a]ctivities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and

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¹⁷⁸ 10 U.S.C. § 980(b) (2012).

¹⁷⁹ *See id.*

¹⁸⁰ DoD Instruction 3216.02, *supra* note 102, § 9(a), at 25.

¹⁸¹ *Id.*, Glossary, at 38.

¹⁸² *Id.*

¹⁸³ *Id.*, Glossary, at 37.

other mission essential personnel under force health protection programs” and field-testing of experimental products.¹⁸⁴

Furthermore, under DOD Instruction 3216.02, an informed consent waiver may be issued if the research meets three required conditions:

1. The research is necessary to advance the development of a medical product for the Military Services;
2. The research may directly benefit the individual experimental subject; and
3. The research is conducted in compliance with all other applicable laws and regulations.¹⁸⁵

The Assistant Secretary of Defense for Research & Engineering maintains the authority to issue an informed consent waiver under this provision, and can delegate this authority to “a DoD Component official who is a Presidential Appointee with Senate Confirmation.”¹⁸⁶ However, informed consent waivers must be placed into context—according to one recent study, on average, 5 out of 6 products under review by the FDA fail to earn regulatory approval because the product is either unsafe or ineffective.¹⁸⁷ As such, the use of non-FDA approved medical products involves significant risk.

D. Military Culture

In addition to military command, an amorphous research/practice divide, and informed consent waivers, military culture is a marker of vulnerability for service members. Specifically, military culture may serve to compel service members to obey a request to submit to medical treatment or to participate in clinical research. As the Presidential Commission for the Study of Bioethical Issues observes:

¹⁸⁴ The broader category also excludes compliance-related activities, program evaluation, outcome reviews, and other activities. *Id.*, Glossary, at 37–38.

¹⁸⁵ *Id.* § 9(c), at 25.

¹⁸⁶ *Id.* § 9(d), at 26.

¹⁸⁷ Leonard Sacks et al., *Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000–2012*, 311 JAMA 378, 379 (2014).

Military personnel also might feel pressure to participate in research because of the structured hierarchy in which they live and work. They might feel that participation could contribute to promotions, easier assignments, or special privileges; or that refusal to participate could result in demotions or other punitive measures. Moreover, the success of military operations depends in part on giving up some individual autonomy for the good of the whole; for this reason, soldiers might be coerced to participate in research if it is considered to be for the greater good; for example, accepting an experimental vaccine to ensure that the entire force would be protected.¹⁸⁸

Army guidelines for clinical investigators echo these sentiments, indicating that service members “are trained to act as a unit, so peer pressure should also be considered and minimized if possible.”¹⁸⁹

As public health experts Victor Sidel and Barry Levy explain in the landmark treatise, *Military Medical Ethics*:

[B]ecause they cannot simply “quit their jobs” or “file a grievance” with a union, government agency, or professional organization, military personnel may not believe that they can truly refuse to participate in these experiments. They may feel more like a “captive audience” than like “volunteers.” Furthermore, they may not be fully informed of the risks for a variety of reasons, including national security.¹⁹⁰

This position is echoed by Paul J. Amoroso and Lynn L. Wenger, who add that “[m]ilitary hierarchy also carries the potential for conflict between the IRB and the commander” and that “[r]esearchers must be especially cognizant of the hierarchical nature of the military and be certain that it does not interfere with the process of informed voluntary consent.”¹⁹¹ The history of research-related exploitation of service members provides a stark reminder of the power of coercion that results from military culture.¹⁹²

¹⁸⁸ PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, VULNERABLE POPULATIONS BACKGROUND 10 (2014), <http://bioethics.gov/sites/default/files/VP%20Bkgnd%20FINAL%20with%20Timeline%2009.21.15.pdf> (citations omitted).

¹⁸⁹ See U.S. ARMY MED. RESEARCH & MATERIAL COMMAND, GUIDELINES FOR INVESTIGATORS: REQUIREMENTS FOR U.S. ARMY MEDICAL RESEARCH AND MATERIAL COMMAND (USAMRMC) HEADQUARTERS REVIEW AND APPROVAL OF RESEARCH INVOLVING HUMAN VOLUNTEERS, HUMAN ANATOMICAL SUBSTANCES, AND/OR HUMAN DATA 15 (2007).

¹⁹⁰ Sidel & Levy, *supra* note 24, at 595.

¹⁹¹ Amoroso & Wenger, *supra* note 15, at 589.

¹⁹² See generally Parasidis, *supra* note 11.

E. Predominance of Force Health Priorities

In the military, there is a “tension between the person who has volunteered as an autonomous individual to undertake the role responsibilities of military service, and the military institution, which must in large part treat service members collectively in order to accomplish its objectives.”¹⁹³ As such, insofar as success in military missions is the driving force underlying the very existence of the military, the maintenance of force-wide health is of primary importance.¹⁹⁴

While public health goals also play a prominent role in civilian medicine, they are more pronounced in military settings. Furthermore, in situations where rationing of health care delivery may be necessary due to resource limitations, the goals of the force take precedent over the health care needs of any one individual.¹⁹⁵

The predominance of force health priorities also impacts the confidentiality of personal medical or health-related information. According to military medical ethicist Michael Gross:

During war and among one’s own soldiers, the scope of the private sphere decreases and that of the public expands as collective welfare takes precedence over an individual’s private good. Thus, a wide range of private information is relevant during war that is not particularly interesting in other settings. This includes a person’s emotional stability, propensity for aggression or unsocial behavior, or difficulty with authority—anything, in fact, that could upset the discipline and cohesiveness necessary to maintain effective fighting capabilities.¹⁹⁶

As Maxwell Mehlman and Stephanie Corley add, because of the priority of the group over the individual, service members “must be defined according to a different ethical principle that is more in keeping with the core values of the military.”¹⁹⁷ These values are

¹⁹³ William J. FitzPatrick & Lee L. Zwanziger, *Defending Against Biochemical Warfare: Ethical Issues Involving the Coercive Use of Investigational Drugs and Biologics in the Military*, 3 J. PHIL., SCI. & L. 1, 3 (2003).

¹⁹⁴ See Mitka, *supra* note 5.

¹⁹⁵ See, e.g., Fitzpatrick & Zwanziger, *supra* note 193, at 3.

¹⁹⁶ MICHAEL L. GROSS, *BIOETHICS AND ARMED CONFLICT: MORAL DILEMMAS OF MEDICINE AND WAR* 121 (MIT Press 2006).

¹⁹⁷ See Mehlman & Corley, *supra* note 94, at 336.

succinctly summarized by Dr. Edmund Howe, a physician, attorney, bioethicist, and professor at the Uniformed Services University of the Health Sciences: “[T]he military physician, at least implicitly, promises to support the mission or greater good when and if this is necessary, even if this requires subordinating the medical well-being of the individual soldier.”¹⁹⁸

F. Governmental Immunities and Limitations on Tort Claims by Military Personnel

A research participant’s ability to seek legal recourse in the event of a research-related injury is an integral component of the legal framework governing research with human subjects.¹⁹⁹ As a non-negotiable component of informed consent, the Common Rule requires that “[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”²⁰⁰

Although the DoD has adopted the Common Rule and this precise language is codified in the DoD’s regulations governing research with human subjects,²⁰¹ a series of governmental immunities and limitations on tort claims render this important provision virtually meaningless. For example, the *Feres* doctrine prevents service members from suing the government, government employees, or agents working on behalf of the government, in situations where a

¹⁹⁸ Edmund G. Howe, *Mixed Agency in Military Medicine: Ethical Roles in Conflict*, in 1 *MILITARY MEDICAL ETHICS* 331, 333 (Thomas E. Beam & Linette R. Sparacino eds., 2003).

¹⁹⁹ See, e.g., David B. Resnik et al., *Research-Related Injury Compensation Policies of U.S. Research Institutions*, 36 *IRB: ETHICS & HUMAN RES.* 12, 12 (2014) (indicating that the Common Rule prohibits “informed consent from including any exculpatory language in which the participant (or his or her representative) waives or appears to waive legal rights or releases or appears to release the investigator, institution, or sponsor from liability for negligence”); Efthimios Parasidis, *Compensation for Research-Related Injuries Involving Human Participants*, 2 *HARV. J. MED. ETHICS* 26, 26 (2001) (stating that regulations preclude researchers from asking that research participants waive their right to sue in the event of a research-related injury).

²⁰⁰ 45 C.F.R. § 46.116 (2015).

²⁰¹ 32 C.F.R. § 219.116 (2015).

service member's injuries "arise out of or are in the course of activity incident to service."²⁰²

Courts have interpreted the *Feres* doctrine broadly, encompassing claims raised by service members who suffered severe injuries after military officials locked them in gas chambers and exposed them to mustard gas against their will,²⁰³ as well as claims raised by soldiers who were harmed by coerced or compelled participation in the military's atomic experiments²⁰⁴ or the DoD's clandestine psychotropic drug experiments.²⁰⁵ In each case, because the conduct occurred while the soldiers were subject to military command, the *Feres* doctrine served to foreclose legal remedies.²⁰⁶ Military medical experts Paul J. Amoroso and Lynn L. Wenger take issue with this line of jurisprudence, and argue that the DoD should "provide extra protections for human subject volunteers because of the *Feres* Doctrine."²⁰⁷

Coupled with the broad immunities provided by the *Feres* doctrine, under the political question doctrine, courts are barred from reviewing military decisions that are political in nature.²⁰⁸ Political questions include instances where it is impossible for a court to render a judgment without making a policy decision that is beyond the court's discretion, or where a court's decision would express a "lack of the respect due [to] coordinate branches of the government."²⁰⁹

In addition to outright dismissal of a case pursuant to the *Feres* doctrine or the political question doctrine, the state secrets privilege

²⁰² *Feres v. United States*, 340 U.S. 135, 146 (1950).

²⁰³ *Schnurman v. United States*, 490 F. Supp. 429, 438 (E.D. Va. 1980).

²⁰⁴ See *Jaffee v. United States*, 663 F.2d 1226, 1229 (3d Cir. 1981).

²⁰⁵ See *United States v. Stanley*, 483 U.S. 669, 672 (1987).

²⁰⁶ See Efthimios Parasidis, *Emerging Military Technologies: Balancing Medical Ethics and National Security*, 47 CASE W. RES. J. INT'L L. 167, 175-76 (2015).

²⁰⁷ Amoroso & Wenger, *supra* note 15, at 588. Amoroso is a physician and Colonel in the Medical Corps, U.S. Army, and is a Research Epidemiologist and Project Director for the Total Army Injury and Health Outcomes Database Project of the U.S. Army Research Institute of Environmental Medicine. Wenger was a Human Research Support Program Coordinator for the Soldiers Systems Command in Natick, Massachusetts. See *id.* at 563.

²⁰⁸ See *Baker v. Carr*, 369 U.S. 186, 227 (1962).

²⁰⁹ *Id.* at 217.

provides the government with the ability to withhold information in instances where officials believe that the information could expose facts that may compromise national security.²¹⁰ The government has invoked the state secrets privilege often, including cases related to rendition, torture, interrogation, warrantless wiretapping, widespread surveillance of American and foreign civilians, drone attacks, and lethal targeting of American and foreign citizens.²¹¹

Courts rarely uphold challenges to the government's assertion of the privilege, though investigators have uncovered instances where the government used the privilege not to protect a state secret, but rather to cover-up wrongful conduct.²¹² The recent controversies surrounding drone-targeted killings and the NSA's surveillance programs are examples of the government using the state secrets privilege to prevent disclosure of facts directly related to legal challenges to the programs,²¹³ and there is nothing that prevents the government from invoking the privilege to withhold information in the event of a research-related injury or a challenge to a research protocol.

III. ADDRESSING RESEARCH-RELATED VULNERABILITIES OF SERVICE MEMBERS

A. DoD Guidelines

DoD guidelines acknowledge that military personnel can be vulnerable to coercion or undue influence, and set forth a number of protections that address some of the markers of vulnerability. For example, pursuant to DoD Instruction 3216.02, "[i]nvestigators, IRBs,

²¹⁰ See, e.g., *United States v. Reynolds*, 345 U.S. 1, 10 (1953); *Tenet v. Doe*, 544 U.S. 1, 11 (2005).

²¹¹ Amanda Frost, *The State Secrets Privilege and Separation of Powers*, 75 *FORDHAM L. REV.* 1931, 1941–46 (2007).

²¹² *Id.* at 1942–50.

²¹³ See Spencer S. Hsu, *Obama Invokes 'State Secrets' Claim to Dismiss Suit Against Targeting of U.S. Citizen al-Aulaqi*, *WASH. POST* (Sept. 25, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/09/25/AR2010092500560.html>; Ellen Nakashima, *U.S. Reasserts Need to Keep Domestic Surveillance Secret*, *WASH. POST* (Dec. 21, 2013), https://www.washingtonpost.com/world/national-security/us-reasserts-need-to-keep-domestic-surveillance-secret/2013/12/21/9d2b4538-6a7e-11e3-a0b9-249bbb34602c_story.html.

IOs, and DoD Component personnel reviewing research protocols shall consider the need” for additional safeguards for “other vulnerable populations,” including “research involving human subjects and investigators in supervisor-subordinate relationships” or “any other kind of human subjects in circumstances that may warrant provision of additional protections.”²¹⁴ DoD policy also indicates that superior officers, in the context of solicitation for participation in research, “are prohibited from influencing the decisions of their subordinates” and “shall not be present at any human subject recruitment sessions or during the consent process.”²¹⁵

At the same time, however, a service member’s decision to volunteer for a research study is subject to that service member’s commander supporting “the member’s participation in DoD-supported research.”²¹⁶ DoD policy mandates that service members “follow their command policies regarding the requirement to obtain command permission to participate in research,” regardless of whether a service member is on-duty, off-duty, or on leave.²¹⁷ This DoD policy applies in equal force to all research, from a study examining traumatic brain injury to a clinical trial for a new vaccine.²¹⁸

While the rationale behind the policy stems from the commanding officer’s responsibility to ensure that those under his or her command are fit to perform their military duties,²¹⁹ a commanding officer’s ability to override a service member’s decision to partake in research adds another layer of vulnerability. Namely, service members are vulnerable to coercion or undue influence that *prevents* them from taking part in research. Furthermore, this policy conflicts with the provision that indicates a superior officer shall not influence a service member’s decision to participate in research.²²⁰

²¹⁴ DoD Instruction 3216.02, *supra* note 102, § 7, at 19–20. An IO is the “senior person authorized to establish and responsible to maintain the HRPP for the institution.” *Id.* Glossary, at 36.

²¹⁵ *Id.* §§ 7(e)(1)(b)–(c), at 23.

²¹⁶ *Id.* § 7(e)(1)(a), at 23.

²¹⁷ *See id.*

²¹⁸ *See id.*

²¹⁹ *See id.*

²²⁰ *See supra* text at note 215.

For service members enrolled in a study “that has been determined to be greater than minimal risk *and* when recruitment occurs in a group setting,” DoD guidelines require that the IRB appoint an ombudsman “to monitor that the voluntary involvement or recruitment of the service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate.”²²¹ Also, for any study involving more than minimal risk, DoD guidelines require the appointment of an independent research monitor, though this person can be an ombudsman or a member of the data safety monitoring board.²²² The duties of the research monitor go beyond those of the ombudsman, and include not only observation of recruitment and consent procedures, but also review of study interventions, data collection, and data analysis.²²³

Research monitors can also interview the human subjects and consult with individuals outside the research.²²⁴ Perhaps most importantly, research monitors can “stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report.”²²⁵ While research monitors play an important role in protecting service members enrolled in research, DoD policy allows for a waiver of the research monitor requirement “on a case-by-case basis.”²²⁶ The guidelines limit the waiver to situations where “the inclusion of a research monitor is not necessary to provide additional protections for human subjects,” but DoD policy does not provide clear guidance as to the parameters that must be satisfied for the issuance of a waiver.²²⁷

²²¹ DoD Instruction 3216.02, *supra* note 102, § 7(e)(1)(d), at 23 (emphasis added).

²²² *Id.* § 8(a), at 24.

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.* § 8(b), at 25.

²²⁷ *Id.*

B. Vulnerability, Service Members, and the Common Rule

Arguably, existing DoD guidelines reflect a reasonable interpretation of the Common Rule's requirement that IRBs provide additional protections for individuals who may be vulnerable to coercion or undue influence. For example, guidelines that restrict a superior officer's role in research participation address the possibility of coercion in the recruitment of service members for research, while the use of ombudsmen or research monitors help ensure that research-related risks are reasonable in relation to the underlying study.²²⁸ In this respect, the DoD guidelines reflect a triumph of institution-derived protections for vulnerable research subjects. At the same time, however, the DoD guidelines do not adequately address all of the military-specific markers of vulnerability.

For example, a superior officer's ability to override a subordinate's decision to participate in research represents a form of coercion and undue influence. Yet, this policy is understandable. The *raison d'être* of service members is to help fulfill the military goals of the armed forces, and enrolling in research may frustrate that goal. The failure of the DoD guidelines to address *all* potentially problematic aspects of the military command structure does not, in and of itself, represent bad faith or an intentional failure to protect the interests of service members. Rather, the failure may be seen as a realistic compromise necessary to harmonize the interests of the armed forces and the military biomedical complex.

While it is unreasonable to expect that research protections can or will eliminate entirely the impact of military command structure and military culture, the inability of guidelines to fully address these issues supports the notion that service members, as a class, are vulnerable to coercion or undue influence. Other factors that support the conclusion that service members are a vulnerable population include the predominance of force-health priorities and the amorphous boundary between research and treatment for military personnel. While these concerns are, to varying degrees, present in civilian contexts, national security law and DoD guidelines exacerbate the concerns for military

²²⁸ *Id.* §§ 7(e)(1)(b)-(d), at 23.

personnel. Field-testing, Emergency Use Authorizations, and informed consent waivers are apt examples.²²⁹

The Common Rule places the legal burden on IRBs to determine whether individuals are vulnerable, and what additional protections are appropriate to address that vulnerability.²³⁰ This represents a flexible approach to research protections for human subjects. It would be impractical, if not impossible, for the Common Rule to outline the precise protections that must be afforded in all circumstances to different subsets of vulnerable populations. Each research project carries its own risks and benefits, and the Common Rule places this fact-based inquiry on the individual IRB reviewing the protocol.²³¹ However, by identifying certain groups as vulnerable populations and setting forth specific guidelines for some of these groups,²³² the Common Rule helps guide IRBs in this process. The identification of specific groups also reflects a recognition by policy-makers that certain groups are *de facto* vulnerable.

With respect to the categories identified in the federal guidelines, “some of the groups could be considered vulnerable because they lack the capacity to provide informed consent to research (e.g., children and mentally disabled persons), or because they are unusually susceptible to coercion (e.g., prisoners).”²³³ For other groups, such as pregnant women, vulnerability is not related to capacity or coercion concerns of the woman,²³⁴ but rather “to protect the fetus from research-related risks.”²³⁵

The diversity of rationales underscores the notion that the Common Rule maintains a flexible standard for determining which groups of individuals constitute a vulnerable population. Still, one

²²⁹ See *supra* Subsections III.A–C.

²³⁰ 45 C.F.R. § 46 (2015).

²³¹ See *id.*

²³² See *id.*

²³³ Coleman, *supra* note 1, at 12.

²³⁴ *Id.*

²³⁵ Sara F. Goldkind et al., *Enrolling Pregnant Women in Research – Lessons from the H1N1 Influenza Pandemic*, 362 NEW ENG. J. MED. 2241, 2242 (2010); see also Karen J. Schwenzer, *Protecting Vulnerable Subjects in Research: Children, Pregnant Women, Prisoners, and Employees*, 53 RESPIRATORY CARE 1342, 1346 (2008).

must also be mindful of the unintended consequences of identifying too many groups as vulnerable. As Levine and colleagues argue, “if everyone is vulnerable, then the concept becomes too nebulous to be meaningful.”²³⁶ Furthermore, and perhaps more importantly, additional protections for some vulnerable populations, such as pregnant women, prisoners, and children, oftentimes have restricted their ability to partake in research, which has led to a lack of data to address the specific medical needs of individuals from these groups.²³⁷ While providing adequate research-related protections is unquestionably important, examining the safety and efficacy of medical treatments available to vulnerable groups is no less meaningful.

At the same time, there is a risk of maintaining too narrow of a definition of vulnerability. One can reasonably assume that the drafters of the Common Rule understood that the statute includes an expansive definition of vulnerability, and that this broad definition was necessary to achieve the fundamental goal of the law, which is to provide safeguards for individuals who participate in research.²³⁸ Importantly, despite ample criticism of the Common Rule’s framing of vulnerability,²³⁹ the NPRM maintains the precise definition of vulnerability that was set forth in 1991 (“likely to be vulnerable to coercion or undue influence”), and in fact clarifies that the most expansive construction of that definition is appropriate.²⁴⁰ As such, it is highly unlikely that OHRP or HHS believes that the concept of vulnerable populations should be interpreted narrowly. Nor should it be. Even if one takes the extreme position that everyone is vulnerable, it does not follow that everyone is vulnerable for the same reason. For example, the concerns of pregnant women differ from the concerns of

²³⁶ Levine et al., *supra* note 44, at 46.

²³⁷ See, e.g., Mary C. Blehar et al., *Enrolling Pregnant Women: Issues in Clinical Research*, 23 WOMEN’S HEALTH ISSUES e39 (2013); Sharon Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 INDIANA L. REV. 475 (2000). For example, a significant number of FDA-approved pharmaceuticals have insufficient data to create an accurate risk-benefit profile for pregnant women. *Id.*

²³⁸ See NPRM, *supra* note 22, at 53,935–42.

²³⁹ See, e.g., *supra* text at notes 78–85.

²⁴⁰ NPRM, *supra* note 22, at 53,987.

prisoners,²⁴¹ just like the needs of the homeless differ from the needs of service members.

While the Common Rule “is frequently described as a risk-based rubric . . . there is very little in the Common Rule itself or subsequent guidance that provides help with defining or assessing risk.”²⁴² Furthermore, as the National Research Council (“NRC”) elucidates, it is important to distinguish “social vulnerability from research vulnerability,” which means identifying “harm that may be caused by the research participation itself and harms that may be caused by the life situation or characteristics of the research participants.”²⁴³ The NRC explains the main difference between the two by clarifying that, while social vulnerabilities are “real,” they “are not caused by the research.”²⁴⁴

In applying the NRC’s guidance to service members, the following considerations are especially relevant: (1) whether service members are vulnerable because of military-specific laws or norms; (2) whether they are vulnerable because of the type of research that they are being asked to participate in; or (3) whether they are vulnerable because they represent a certain segment of society. In other words, as applied to service members, the concept of vulnerability can be theorized as being linked to some form of coercion, factors that limit or interfere with the ability of service members to provide informed consent, or socio-economic or cultural aspects of service members that make them vulnerable because of who they are.

Although some experts advocate for drawing a distinction between vulnerability based on life characteristics and vulnerability based on the research itself,²⁴⁵ a failure to take social vulnerability into consideration may propagate inequalities and disparate treatment of

²⁴¹ Though not a perfect fit, an analogy to prisoners raises interesting parallels. Service members may also be deemed a captive population, given the UCMJ and the rigors of military hierarchy. And, like prisoners, service members also rely on their institution for the provision of health care (which contributes to the blurring between treatment and research) and may view participation in research as a break from day-to-day routines.

²⁴² NRC Report, *supra* note 83, at 59.

²⁴³ *Id.* at 67.

²⁴⁴ *Id.*

²⁴⁵ *See, e.g., id.*

marginalized populations. For example, studies have consistently found that the odds of a person entering the military are correlated with family background, race, family structure, and parental education.²⁴⁶ African-Americans are over-represented in the military – in 2010, African-Americans comprised 17% of the armed forces and 12.6% of the general population.²⁴⁷ African-American women are enlisting in the military at a rate far higher than Caucasian or Hispanic women; 31% of women service members are African-American, which is double the percentage of the civilian female population that identifies as African-American.²⁴⁸ By contrast, Caucasian women represent 53% of the women in the military while accounting for 78% of the female civilian population.²⁴⁹ Insofar as the demographics of the U.S. military reflect and/or reinforce socio-economic disparities, officials have a moral obligation to ensure that federal regulations recognize these factors and provide adequate safeguards for service members.

As military medical ethicist Michael Gross observes, “during armed conflict, there is very little compunction about using persons as means.”²⁵⁰ While combat-related risks are an inseparable aspect of life

²⁴⁶ See Alair MacLean & Nicholas L. Parsons, *Unequal Risk: Combat Occupations in the Volunteer Military*, 53 SOC. PERSP. 347, 359–60 (2010). Individuals who grow up in families with lower socioeconomic status are more likely to enlist in the military, while citizens in the top income distribution are under-represented in the armed forces. Those who enlist in the military are less likely to have grown up with both biological parents and are more likely to come from families where the parents had less education. Service members have poorer high school grades than the general population and high school students with college ambitions are far less likely to enroll in the military. When compared to the general population, enlistees had fewer years of education and were more likely to have dropped out of high school. See *id.* at 349, 360, 366; Amy Lutz, *Who Joins the Military?: A Look at Race, Class, and Immigration Status*, 36 J. POL. & MIL. SOC. 167, 184–85 (2008).

²⁴⁷ See OFF. OF THE DEPUTY UNDER SEC'Y OF DEF., DEMOGRAPHICS 2010: PROFILE OF THE MILITARY COMMUNITY 20 (2011), http://www.militaryhomefront.dod.mil/12038/Project%20Documents/MilitaryHOMEFRONT/Reports/2010_Demographics_Report.pdf; SONYA RASTOGI ET AL., U.S. CENSUS BUREAU, THE BLACK POPULATION: 2010, at 3 tbl.1 (2011), <https://www.census.gov/prod/cen2010/briefs/c2010br-06.pdf>. This equates to over-representation of approximately 35%.

²⁴⁸ See James Dao, *Black Women Are Joining the American Military at a Disproportionate Rate*, N.Y. TIMES, Dec. 23, 2011, at A14.

²⁴⁹ See *id.*

²⁵⁰ GROSS, *supra* note 196, at 171–72.

in the military, does the same hold true for risks from research-related activities? To the extent a distinction should be drawn between combat-related risk and research-related risk, what regulatory safeguards are sufficient to balance the rights of service members and the goals of national security? What remedies should be available to service members if those protocols are breached?

The answers to these questions not only guide IRB consideration of research involving service members, they also help frame the following considerations: (1) whether service members should be specifically identified as a vulnerable population in the Common Rule; and (2) whether 45 C.F.R. Part 46 should include a new regulatory subpart that deals exclusively with research-related concerns of service members.

CONCLUSION

The U.S. military has a long and checkered history of research involving service members.²⁵¹ While DoD guidelines provide some research-related protections for service members, these protections do not fully address military-specific markers of vulnerability. In addition, the DoD has the discretion to amend the guidelines,²⁵² so the protections lack a legal permanence when compared to the protections outlined in the Common Rule and related Subparts.²⁵³

By specifying that service members are an example of a vulnerable population, federal law would not only acknowledge the DoD's past wrongs in the context of human subjects research, it would create a more permanent regulatory framework governing research involving service members.²⁵⁴ Given OHRP's extensive efforts to amend the

²⁵¹ See generally Parasidis, *supra* note 206; Parasidis, *supra* note 11; Efthimios Parasidis, *Human Enhancement and Experimental Research in the Military*, 44 CONN. L. REV. 1117 (2012).

²⁵² See *DoD Issuances*, U.S. DEP'T OF DEF., <http://www.dtic.mil/whs/directives/index.html> (last visited July 18, 2016).

²⁵³ Of course, the federal protections also can be amended, as evidenced by the ANPRM and NPRM. However, the process for amending the federal regulations, when compared to DoD issuances, is more transparent and contains a robust public dialogue, including a period for public notice and comment.

²⁵⁴ Such an amendment also will place the Common Rule in line with other codes governing research with human subjects, such as that set forth by the Council for International

Common Rule to make it more in line with contemporary trends and concerns in human subjects research, it is an opportune time to include service members as an example of a population that is vulnerable to coercion or undue influence. This will serve to memorialize what has already been widely acknowledged by the DoD and other experts,²⁵⁵ and will provide military personnel with additional confidence that government officials understand and appreciate the research-related risks that service members face. Importantly, characterizing service members as vulnerable does not represent an emasculation of warfighters, but rather is likely to contribute to warfighter empowerment.

An amendment to the Common Rule may also open the door to a discussion of whether the unique research-related concerns faced by service members warrant the creation of a new Subpart to 45 C.F.R. Part 46. A new regulatory Subpart could be modeled on the existing Subparts, and could include protections such as: (1) requiring that military IRBs include service members or service member representatives; (2) requiring that military IRBs provide assurances that (a) risks to human subjects are commensurate with non-military studies, (b) the decision to participate will not impact mission or career prospects, (c) confidentiality will be preserved, and (d) follow-up medical care will be provided; and (3) requiring the mandatory use of research monitors. Of course, including service members in the Common Rule as an example of a vulnerable population does not require that an additional Subpart be created—there are other categories of vulnerable populations (namely, “physically or mentally disabled persons” or “economically or educationally disadvantaged persons”) that are identified in the Common Rule as such, yet do not have a distinct Subpart.

Protecting vulnerable populations is one of the primary functions of federal guidelines governing research with human subjects. While identifying service members as a vulnerable population is not a

Organizations of Medical Sciences (“CIOMS”) or the Joint United Nations Programme on HIV/AIDS (“UNAIDS”), both of which identify service members as a vulnerable population. See Jason Andrews, *Research in the Ranks*, 49 PERSP. BIOLOGY & MED. 35, 38 (2006).

²⁵⁵ For example, the President’s Commission for the Study of Bioethical Issues identifies service members as an example of a “potentially vulnerable” population. See PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 188, at 10.

panacea,²⁵⁶ a barometer of the regulatory regime is how well it comports with foundational ethical principles and the real-world system of human subjects research. As such, regardless of whether amendments to federal law are adopted, the DoD should revisit its policies to ensure that the policies adequately address the markers of vulnerability for service members. Just as the United States calls on its military personnel to protect U.S. interests at home and abroad, service members and the public must call on U.S. officials and lawmakers to ensure that the U.S. is adequately protecting members of the armed forces.

²⁵⁶ For one, service members are not a monolithic group. Also, the Common Rule itself has its limits, as it places the legal burden on IRBs to consider appropriate protections.