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Cover Page Footnote

Harwood Garland graduated from the University of California, Irvine with a Bachelor of Arts in Cultural Anthropology (2016) and a Master of Arts in Medicine, Science & Technology Studies (2017). He is currently pursuing a Master of Science in Biomedical and Translational Sciences from the UC Irvine School of Medicine. Special thanks to the University of California Irvine School of Medicine Biomedical and Translational Science Program for their generous financial support of this research.

Extended Commentary: Military Service without the Common Rule

Madison Powers, a senior research scholar at the Kennedy Institute of Ethics and a professor of philosophy at Georgetown, wrote that “Reliance on individual consent alone is not adequate to protect persons from exploitation under conditions of grossly unequal bargaining power, information, and human need.”¹ According to such reasoning, and as a conscionable reaction to medical research atrocities such as those of the Tuskegee Syphilis Study and the Nuremberg Trials, the United States Department of Health and Human Services (HHS) developed the *US Federal Policy for the Protection of Human Subjects*, also known as the “Common Rule” (45 CFR 46) to throttle researches involving those most vulnerable to exploitation. Subparts of the Common Rule prescribe protections for pregnant women, human fetuses, neonates, prisoners and children.² The Common Rule does not mention military service members, and hence does not protect them as a vulnerable class of people. Other laws offer protection in relations to clinical research on U.S. military service members, but they are far from the straightforward protections offered by the Common Rule. 21 CFR Parts 50 and 312, which govern the Food and Drug Administration (FDA), for example, states: “Under the Defense Authorization Act, the President is authorized to waive the Federal Food, Drug, and Cosmetic Act's...informed consent requirements in military operations if the President finds that obtaining consent is infeasible or contrary to the best interests of recipients and on an additional ground that obtaining consent is contrary to national security interests.”³ As military member’s employer, the Department of Defense (DOD) forces service members to continue their voluntary service under threat of legal penalty, dictates much of the living arrangements of service members (such as whether a service member lives in Hawaii or Iraq or on a ship) and —this is a

key component— *provides healthcare* to the service member, may legally request that the president override a service member's wish to receive or not to receive experimental medicines.

There is great practicality to the waiving of a service member's right to refuse medical care, but there is also great risk in dismissing the importance of this step. This risk is what makes service members—and especially junior enlisted service members—a class of individuals vulnerable to research exploitation and warrants consideration for their protection under the Common Rule. For example, in 1802 a French army invaded Haiti to restore French authority over the island and bolster French forces in the New World. Before the worst of the fighting began, an enormous portion of the French army was hospitalized with yellow fever. As a result the French lost control of Haiti and Napoleon cut his losses by selling the Louisiana Territory to the United States in 1803. If a useful immunization had then been available, Napoleon would have ordered his military physicians to prescribe the immunization to his soldiers so long as the number of soldiers expected to die from the immunization was tolerable. Had the French army been immunized, the Haitian forces would likely have been defeated and the history of the New World set on a much different course. A soldier who refused the immunization under these conditions would have been court-martialed and either discharged or forced to receive the immunization anyway—as receipt of this medicine was tactically essential to military achievement. Tactical necessity trumps individual rights in the military—such is the price of victory.

Over the next century, yellow fever epidemics continued to flare up in the New World. Construction of the Panama Canal had to be abandoned because yellow fever was killing so many workers. Epidemics in Memphis, Philadelphia, and many other cities left thousands dead or crippled. In 1900 Dr. Walter Reed (for whom the Army Hospital in Maryland is named) was

charged by the US Surgeon General to find a solution to yellow fever epidemics. Dr. Reed formed the Yellow Fever Commission in Cuba and set to work. In one experiment, U.S. Army and local volunteers lived in confined areas for twenty days, and were exposed to either fomites (clothing and pellets of black vomit from other YF patients) or mosquitoes infected with yellow fever. Sixteen American service members, including John Kissinger—farm boy from Indiana—volunteered for such experiments in which the expected death rate was 20 to 40 percent.⁴ John Kissinger contracted yellow fever and was left paralyzed as a result of the experiments. He was awarded the Medal of Honor for his bravery.

Although the nature of Dr. Reed's authority over the men in his unit was subject to all applicable Army regulations and was legally restricted to his objective, Dr. Reed was still a commissioned officer (promoted to Major in 1893) on an Army base, and he was looking to recruit volunteers for dangerous experiments. Dr. Reed was also a physician acting as the primary investigator of his own clinical experiments. Even if Dr. Reed was capable of separating his medical authority (expertise) from his military authority (rank), the junior-enlisted soldiers could not have been expected to make the same distinction. "Enlisted soldiers who were asked to participate in a potentially deadly experiment by their superior officers may have interpreted such requests as orders; vulnerable, poor newcomers recruited with tempting offers of \$200 in gold coins for participation and bonuses if they contracted the malady (a sum many times more than their annual incomes) were not exactly giving their consent freely either."⁵ Dr. Reed believed it was necessary to tolerate the deaths of three to six of the sixteen junior-enlisted volunteers. He was ethically obligated to accept volunteers only—and even provided translated consent forms to volunteers—but was it even possible for the young soldiers volunteers to give un-coerced, informed consent? Bernard Lo, MD notes that "Although informed consent is legally

required, many physicians are skeptical because patients can never understand medical situations as well as doctors and because they can usually persuade patients to follow their recommendations.”⁶ The doctor’s ability to influence patients is potentially even greater in the relationship between a commissioned officer and a junior-enlisted soldier, sailor, marine, or airman. Dr. Reed and the rest of the Yellow Fever Commission demonstrated that the *Aedes aegypti* mosquito was the primary vector for yellow fever. Policies predicated upon this precious knowledge saved thousands of lives over the entire globe.⁷

Some institutions recognize that technical expertise and military rank can be detrimental to the safety of subordinate subjects. For example, the University of Utah IRB stipulates that when conducting research involving DOD personnel “Officers are not permitted to influence the decision of their subordinates; Officers and senior non-commissioned officers may not be present at the time of recruitment; Officers and senior non-commissioned officers have a separate opportunity to participate and; When recruitment involves a percentage of a unit, an independent ombudsman is present.”⁸ In today’s military, JAG officers, line officers, chaplains, and medical officers, wear the rank of commissioned officers (lieutenant, captain, major, etc.). For junior enlisted personnel, the distinguishing insignia of the officer’s specialty (a laurel wreath for a lawyer, an oak leaf for a physician, etc.) only tells them what the officer is specifically useful for and does *not* communicate a set of unique standards for distinguishing ethical and lawful orders from unlawful or unethical orders based on that officer’s insignia. Thus the junior enlisted personnel are vulnerable to exploitation by the system they are confined to and deserve a source of legal protection other than their employer—the Department of Defense.

Recent Military Clinical Trials

Today, clinical trials in the United States are governed by institutional review boards (IRBs), whose conduct is officially regulated by the Department of Health and Human Services (HHS). Ethical catastrophes demonstrate that an institution, no matter how large or small or well-intentioned, is so essentially biased toward its own aims that an institution cannot be trusted to ethically guide itself and ought to have at least some ethical oversight from a disinterested entity, as can be seen in several cases.⁹ Medical catastrophes sometimes lead to the establishment and imposition of new ethical codes such as the Belmont Report (a parent of the Common Rule) and the Nuremberg Code, precisely because institutions cannot be trusted to govern their own ethical conduct and must be governed by a third party that can balance societal and individual risks and benefits.¹⁰

Research on military personnel is governed in part by DoD Directive 3216.02 *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*¹¹ and DoD Directive 6200.2 *Use of Investigational New Drugs for Force Health Protection*.¹² The former states:

“Investigators, IRBs, Ios [Institutional Officials], and DoD Component personnel reviewing research protocols shall consider the need for appropriate similar safeguards for other vulnerable populations, such as: research involving human subjects and investigators in supervisor-subordinate relationships, human subjects with decisional or mental impairments, human subjects with a physical disability, or any other kind of human subjects in circumstances that may warrant provision of additional protections. As appropriate, qualified individuals (e.g., research monitors, ombudsmen, advocates) may be appointed to perform oversight functions or assist the human subjects.”¹³

When the subjects and investigators are all members of the DOD, regulation must come from an external source, not the DOD. The Department of Defense conducts a vast amount of research, so this is not something that can be casually governed. The DOD employs over three million people, and in 2017 alone had an annual research budget of \$76.2 billion.¹⁴ The Human Research Office of the DOD supervises and publishes research on military personnel and third parties.¹⁵ The US military also conducts one of the world's largest research programs on biomedical enhancements.¹⁶ The Walter Reed Army Institute of Research regularly conducts research on comprehensive soldier fitness, brain injury, sleep deprivation, and works to develop vaccines and drugs for prevention and treatment for malaria, HIV/AIDS, dengue fever, wound infections, leishmaniosis, enteric diseases, and others. WRAIR includes an insectary for raising flies and mosquitoes, a bioproduction facility, resources for conducting clinical trials (both in the U.S. and abroad), and has a multidrug-resistant repository and surveillance network. Another branch of the DOD maintains a serum repository, replete with its own ethical concerns.¹⁷ DOD employees are protected by the DOD's Common Rule provision (Title 32 CFR, Part 219, governs the Department of Defense and §219.101 *Protection of Human Subjects*, restates the Common Rule) and are not at any unusual risk of being exploited by their employer but military service members, and especially the largely uneducated junior-enlisted service members, are confined to service for the duration of their voluntary enlistment under 10 USC 86.886(2), (also known as UCMJ Article 86). Junior enlisted military service members employ such foreshortened bargaining power against the DOD that outside protections are essential.

Dazzling discoveries shadowed by egregious conduct among military research is not new. The "blood bank," for example, was developed in large part to help soldiers during the First World War,¹⁸ as were dozens of advancements in plastic surgery. Submarine technology led to

ultrasound machines. These accomplishments were accompanied by experiments with mustard gas, radiation, and lysergic acid diethylamide (LSD).¹⁹ Knowledge of early anti-malarial drugs and yellow fever vectors (as discussed above) were expensive facts that we largely owe to military research and researchers. A more detailed history of military research can be found in *Justice and Beneficence in Military Medicine and Research*.²⁰

Promising clinical trials can be fast-tracked in the military to get the technology to the front lines, and medical training can be expeditiously completed. If a service member perceived a risk (either by informed consent or other means) and desired to refuse to perform the task (eat the food, sign a consent form, breathe the gas, etc.) the service member may pre-emptively consider it a violation of a lawful order, which is a unique quandary for clinical trials among military service members. If that service member did refuse the treatment, and the order was later judged to have been lawfully permissible, then the service member could face charges under the UCMJ. Even if a service member is informed of risks, they are never entirely free from reprisals for refusing to give consent, and it is therefore unconscionable to have the DOD regulate research on DOD employees. Supervision from the VA, for example, might improve continuity of care for junior enlisted service members after they finish their enlistments.

Madison Powers, the professor of ethics whose words introduced this essay, went on to clarify that “Under such conditions of inequality, some persons will bear greater burdens and receive fewer benefits of social cooperation. Justice therefore demands more than mere noninterference with voluntary agreements. Some role for government or other intervening institution is needed to police such agreements and to protect against exploitation.”²¹ Soldiers represent a population made vulnerable by their subordination within a bureaucracy that, when absolutely necessary, prioritizes mission completion over employee health (again, such is the

nature of the military). Adapting the Common Rule to include protections of junior enlisted service members would not clarify the gray area between commissioned officer and medical provider but such an adaptation would limit the clinical risks to which junior enlisted personnel are exposed.

ENDNOTES

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