

## Liberating the Oppressed

### Research Knowledge Differentials and Ethical Investigation in Special Operations Forces Clinical Science

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#### ABSTRACT

Special Operations Forces (SOF) medics do not have preparation in research knowledge that enables them to independently initiate or generate their own studies. Thus, medics rely on evidence generated by others, who are removed from medics' practice environment. Here, salient literature on research self-efficacy and the genesis of institutional review boards (IRBs) are reviewed and interpreted for contextual applications to medics' practice and initiation of studies. More publications delving into research methods are warranted to promote medics' participation and initiation of self-directed scientific investigation, in collaboration with research scientists.

**KEYWORDS:** *Special Operations; ethics; medics, military; research; research self-efficacy*

#### Introduction

Most believe that scientific research is "honest and self-correcting"<sup>1</sup> despite recently reported research misconduct attributed to elements such as poor mentorship, unclear ethical awareness, and a combination of self-induced perfectionism and external expectations.<sup>1</sup> Many research and clinical environments inadvertently induce subordinates to unquestioningly accept the decisions and opinions of those with higher rank or perceived expertise.<sup>1</sup> The power differentials inherent within the military rank structure can thus negatively affect novice researchers and clinicians of enlisted rank. This discussion is the first in a series about the research dynamics and processes important to advancing medic-driven SOF clinical research. Specifically, the power dynamics of rank and research knowledge are identified as barriers to medics producing research output.<sup>2</sup> An historical overview of research ethics is presented to introduce the IRB and the main principles of what developed into informed consent.

#### Background

End-users of SOF research are medics,<sup>3</sup> which immediately assigns rank, despite the known disconnect between rank and authority. The reality is that SOF medics are enlisted and, therefore, in theory, hierarchically subordinate to commissioned officer clinicians. In no way is that statement intended to denigrate the clinical acumen or authority of enlisted medics, but it demonstrates an immediate power differential in SOF-specific clinical research. A analysis of 2 years of article authorship in the *Journal of Special Operations Medicine* estimated that less than 13% of authors are medics and less than 7% of primary authors are medics.<sup>4</sup> This is likely due to two factors: those with doctoral qualifications are statistically more likely to generate research output because they are able to invest more time toward research and their work obligations provide more time to conduct research.<sup>5</sup> The biggest predictors of research output are one's believed ability to conduct research (research self-efficacy), interest in producing research, having the time to conduct research (versus clinical practice and other work tasks), and the demographic factors of rank and qualifications.<sup>5</sup>

#### Knowledge Is Power

Within any organization, the key to equalizing power differentials is knowledge. Basic research knowledge is typically taught in undergraduate degree programs (4-year university programs), although research ethics and methods are usually taught at the graduate level (master's-level nurse practitioners and physician assistants); general biostatistics are included in clinical doctorates (e.g., MD, DNP, and DPT degrees); and advanced multivariate statistics are reserved for doctoral degrees in research science (e.g., PhD). Designated doctrine for enlisted military occupational specialties does not typically include content on research or how studies are generated or statistical analyses performed. Thus, most

enlisted medics likely rely on the perceived research acumen of commissioned clinicians, who, without a PhD, themselves may not have the research preparation that those junior to them assume them to have. Interpreted broadly, such research knowledge differentials oppress and prevent knowledge generation from medics, who then must rely on persons prepared at the doctoral level, who are likely far removed from medics' battlefields of practice.

### Ethical Research: The Basics

Ultimately, adhering to research ethics depends on the person conducting the research. More than 60% of research misconduct relates to individual failure to follow ethical guidelines and to accurately report results.<sup>1</sup> The Nuremberg Code outlined three fundamental rights for human subjects in research situations: "voluntary and informed consent, a favorable risk-to-benefit analysis, and the right to withdraw without repercussion."<sup>6</sup> Primarily, the Nuremberg Code was created in response to the war crimes trial (Nuremberg trials) after World War II, during which prisoners of war were subjected to inhumane experiments under the guise of medical research.<sup>6</sup> Despite US government influence in the Nuremberg trials, the United States did not adopt full research regulations after the Nuremberg Code's creation,<sup>6</sup> and those three fundamental rights did not protect research participants from experimental harm.

In 1964, the World Medical Association met in Helsinki, Finland, and added two codicils to the Nuremberg Code: the interests of the subject should always be placed above the interests of society, and every subject should receive the best known treatment<sup>6</sup>; although these were positive additions, the result was far from comprehensive protection. This prompted a 1966 review of unethical research by Dr Henry Beecher in the *New England Journal of Medicine*, which concluded that the ethics of a study should be determined at its genesis rather than at its conclusion and that the lack of informed consent is harmful to participants.<sup>6,7</sup> Senator Ted Kennedy spearheaded the National Research Act of 1974, which led to the 1978 report of principles guiding ethical research conduct, known as the Belmont Report.<sup>6</sup> The Belmont Report delineated minimum requirements for ethical human subjects research: autonomy, beneficence, and justice.<sup>6</sup>

These regulations were in response to several examples of unethical conduct; two are highlighted here in brief—the Tuskegee experiments and the Willowbrook study. In the Tuskegee experiments, poor minority (African American) men were promised treatment for nonspecific hematological disorders and then were infected with syphilis.<sup>8</sup> The treatment—simple penicillin—was withheld from those infected, and the participants were

never informed about the risks, procedures, research plan, or possibilities of sustained damage to them or their partners.<sup>8,9</sup>

In the Willowbrook study, institutionalized residents with profound intellectual and developmental disabilities—mostly children—at a state hospital were infected with hepatitis passively and even purposely infected via fecal-oral routes.<sup>7</sup>

Like the Tuskegee experiments, the participants were never informed of the protocols or risks, nor were the family members responsible for their decisions, as the participants were vulnerable and unable to make decisions for themselves. Coercion was also used as a tool for recruiting participants, as the parents of the children were told they could skip the long waitlist for a facility short on beds if they allowed their children to participate.<sup>7</sup>

Both instances developed our current standards for ethical research by demonstrating the severe harm that results from denying self-governance and self-determination and obfuscating the risks and benefits from participants. In these two examples, the ethical violations were similar and the participants were (at that time) "devalued members of society."<sup>8</sup> The subversive way in which participants were recruited, through deception and coercion, exemplifies how such dishonesty can severely harm populations, regardless of their mental capacities. In the Tuskegee experiment, the poverty of the participants was used as a tool against them (i.e., the participants were not able to advocate for themselves in determining their ability to refute what educated physicians were imposing on them). Neither study provided informed consent to the participants, and their vulnerabilities were used as tools against them. After the misconduct from these studies was made publicly known, the government outlined the principles and regulations proposed through the Belmont report. This report spearheaded the federal guidelines for human subjects research and the requirements now presumably found within every IRB.

For a person to have autonomy, he or she should be treated in a manner that allows him or her to govern his or her own decisions through understandable and thorough information via informed consent, in addition to ensuring that no coercion or deception is practiced.<sup>9</sup>

"Autonomy" also refers to the respect given to a person's right to the truth. In the Tuskegee experiment, deception was present in the misinformation provided to the participants in that they were told blood tests would be provided for "bad blood"—at the time (the 1930s), that misnomer referred to a constellation of clinical syndromes in addition to syphilis. From a social justice

perspective, poor black men in the South, especially in the 1930s, were likely to be undereducated and possibly illiterate. The lack of informed consent in language understandable to the participants is a prime example of deception and misinformation. In fact, the director of the Tuskegee experiment, Dr Sidney Olansky, stated that the participants' illiteracy was a boon to the experiment's length, as the participants could not read newspapers and determine that they were susceptible to diseases written about publicly.<sup>9</sup>

In the Willowbrook study, the participants were vulnerable in their mental capacities and could not self-govern. Their powers of attorney, or the family members making decisions for them, were denied information and were deceived by the investigators as to the conditions to which the children would be exposed. More so than even the Tuskegee experiment, the children at Willowbrook were coerced into participation as their parents were promised coveted admission to the hospital or threatened with expulsion for participation or nonparticipation in the study, respectively.<sup>8</sup>

Although considered monstrous acts of unethical research now, at the time, no actionable standards existed for protecting autonomy, beneficence, and justice in human subjects research. Within the contexts of those studies, the participants were considered at that time to be noncontributing members of society and somehow subhuman. African Americans could not vote then in rural Alabama, and persons with intellectual disabilities were termed "mentally defective." The Americans with Disabilities Act did not yet exist. Marginalization that occurred then can still occur now: with enemy combatants, illiterate villagers, and less-developed coalition forces deemed backward or somehow less-than by first-world Westerners. Even in some military publications and presentations, photographs of wounded local nationals or combatants are often not blurred out, nor are their physical identities fully protected.

Simply put, vulnerable populations are those who are relatively or absolutely incapable of protecting their own interests.<sup>10</sup> That description likely encapsulates a majority of oppressed peoples with whom SOF work in differing theaters and contexts.

## Informed Consent

History has a tendency to gloss over the brutalities experienced by human participants in early medical research. During his time as a bacteriologist in Cuba, Walter Reed infected (believed now through purposeful exposure) dozens of immigrant workers with yellow fever.<sup>11</sup> Examples of humans' forced participation in research without knowledge of the risks haunt scientists to this

day. This stresses the importance of the IRB. More than 30 years ago, the US Department of Health and Human Services established the federal standards for human subjects research.<sup>12</sup>

At the local level—university or hospital—these standards are enforced by the IRB.

The first step in ethical research, other than an overall responsible research design, is the statement of informed consent. This "common rule" applies to all research involving human subjects, even if it is a case study or survey research. Under the Common Rule, participants must receive thorough information about the potential risks and benefits of participating in the research, must be allowed to refuse to participate without penalty, and must give informed consent to the researcher.<sup>12</sup> Individual IRBs will have statements of informed consent that differ slightly, but all statements incorporate the elements of autonomy, beneficence, and justice.

## Do You Need an IRB to Approve Your Study?

The short answer is yes, and always yes. At the minimum, you need the IRB to tell you that you do not need the IRB: only the IRB can tell you that you are exempt from their oversight. This is where it gets confusing. Like research itself, the IRB process can be a bit tedious to deal with—statements, forms, and permissions are time-consuming and can delay starting research—and some might seek to avoid needing IRB approval, as they assume their study is an "internal quality improvement" (QI) project, which previously was assumed to be exempt from the IRB's supervision. That is still somewhat true, but only if your QI project is literally going to stay within your department or institution and never be shared externally. If your study involves humans or human data (including chart reviews, registry data, or aggregated patient data), send the proposal to the IRB. If there is a possibility to publish or present your study, send the proposal to the IRB. If you are unsure if your project is QI or research, send the proposal to the IRB. It is better to seek approval and be told you do not need it than to have a study or publication embarrassingly retracted, or rejected by a journal's peer-review panel, because you did not seek IRB approval first.

## Conclusion

This is the first of several articles intended to educate SOF medics and clinicians about generating valid research from their own experience and practice. By no means is it an exhaustive interpretation of the storied history of research ethics and/or misconduct. Gratitude is due to the medics and providers pushing the envelope every day in practice.

## Disclosure

The authors have nothing to disclose.

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