

Human Subjects in Weapons Research

The threat that biological and chemical weapons might be used in the context of armed conflict or by terrorists is frighteningly real. Advances in genetics, microbiology, bacteriology, and cognate areas of biomedicine are presenting a new array of threats to both military personnel and civilians. Synthetic virulent strains of viruses and bacteria, "fusion" toxins, and stealth viruses, along with novel modalities for delivering toxic agents using organic and inorganic chemicals, foods, aerosols, and microdroplets, have raised the concern of federal and state governments, national security agencies, and the armed services. Research efforts, supported by significant federal and private funding, are underway to find vaccines, drugs, prophylactic agents, and palliating interventions that might mitigate these threats.

The explosion of research in this area has created an important but little-discussed ethical challenge. Many institutions are struggling with issues raised by the design and oversight of research protocols that call for the deliberate exposure of human subjects to toxic and noxious agents. Some of this research will of necessity be done secretly, despite the fact that, as at least one federal panel noted nearly a decade ago, this poses a tension "between duties to disclose and the need to keep information secret."* Federal regulators and scientific and medical journals will soon be asked how to ensure that such experiments are carried out in a way that is consistent with the highest standards of ethical conduct in the protection of human subjects.

Contemporary human subjects protections apply almost exclusively to research that seeks to produce generalizable knowledge that can be put to beneficial use in biomedicine; for example, by creating new diagnostic tests, new therapies, or new forms of prophylaxis against naturally occurring diseases. Review bodies and regulators assess informed consent and risk/benefit ratios in the context of research to improve health. There is little experience with experiments that deliberately harm subjects.

Such experiments have, for the past two decades, been limited to three areas. The first is research on treatments for common nonlethal viruses, which requires first infecting subjects. The risks to subjects in these types of studies are known to be very small. The second is "Phase One" clinical trials, done to assess the safety of new drugs. The third is challenge studies, in which basic physiological and psychological information is sought about reactions to various stimuli. Current ethical standards require that subjects in such studies be closely monitored and that risks be kept to a minimum.

Research involving biological or chemical weapons must necessarily involve exposures to toxic agents and levels of risk higher than those that exist in most research. Such research would seem to compromise the core tenet of medical ethics that studies should not knowingly do harm. Indeed, the Environmental Protection Agency now refuses to accept toxicity tests done on human subjects in order to establish "safe levels." Yet national security now places a higher premium on studies that might pose similar risks, and many prospective subjects might wish to volunteer from a sense of duty or patriotism or for personal financial gain.

There is every reason to believe that such work will move forward rapidly. If so, clear guidelines are needed for establishing its unequivocal relevance to national security concerns. These guidelines must also address who may be recruited as subjects, what level of competency they should demonstrate, how the freedom of their choice can be ensured, what types of end points will be used, what compensation they will be given, and what level of oversight will be in place. Investigators, review committees, and journal editors will need guidance about the kinds of harm that can be associated with this research and the ways in which restrictions on the dissemination of research results should shape their assessment of its morality.

Some will surely argue that no form of research involving the deliberate harm of human subjects ought to be tolerated. Such a policy could be put in place. It would have obvious implications for the speed with which antidotes to biological and chemical weapons can be found and the confidence that those receiving them can have in their efficacy. If, on the other hand, the need to hasten discovery in this area leads us as a nation to permit such research, it is imperative that the norms needed to ensure that it is conducted fairly and humanely be formulated, then widely discussed and thoroughly debated as soon as possible.

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*U.S. Department of Energy, *Advisory Committee on Human Radiation Experiments—Final Report*, vol 1., chap. 14. Available at <http://tis.eh.doe.gov/ohre/roadmap/achre/report.html>