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Public Trust as a Policy Goal for Research With Human Subjects

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In his insightful essay, “The Case for Evidence-Based Rule-making in Human Subjects Research,” Benjamin Sachs (2010) argues that documents that guide research with human subjects, such as the Nuremberg Code, the Helsinki Declaration, and the Belmont Report, should be viewed not as stating ethical rules but as stating policy rules, because they are not based on ethical obligations but rather have been promulgated to achieve policy objectives. Sachs argues that society should develop rules for research with human subjects that foster legitimate goals based on empirical evidence. If evidence shows that a particular policy is not achieving its goals, the policy should be modified.

Sachs’s argument rests on a distinction he draws between ethical rules and policies. Ethical rules have normative force (i.e., justification), he argues, because they are based on ethical obligations, whereas policies have normative force because they are promulgated by particular groups to achieve goals. I am not convinced that a sharp distinction can be drawn between ethical rules and policies, because many ethical obligations are justified because they help to promote particular goals or outcomes. For example, the obligation to help other people can be justified because it produces positive results (i.e., happiness, avoidance of harm, etc.). Ethical rules, according to this view, are a mix of categorical imperatives justified without reference to their likely consequences and hypothetical imperatives justified by reference to their likely consequences (Ross 1930). If the normative force of a rule depends on its ability help us achieve a particular goal, it makes little difference whether we call it an ethical rule or rule of a policy, because this linguistic maneuver will not affect its justification.

I will not challenge Sachs’s distinction between ethical rules and policies or critique his provocative claim that the “ethical” rules found in guidance documents are not really ethical rules at all. Instead, I would like to focus on an important aspect of his view, namely, the idea that rules for the protection of human subjects in research—whether we call them ethical rules or policies—should promote important goals. If we accept this assumption, it follows that special attention should be given to clearly formulating these goals and drawing implications from them for policy development.

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There are several well-recognized goals for the rules to protect human subjects in research. One of these goals—the most important one, I believe—is to protect the rights and welfare of human beings. History teaches us that many of the landmark ethics documents were written in direct response to violations of human rights in research, which resulted in significant harm, or death. The Nuremberg Code was drafted during the Nuremberg Trials, in which German military personnel, political leaders, and others were convicted of war crimes. The drafters of the code were responding to the atrocities against concentration camp prisoners committed by Nazi physicians and scientists during World War II in the name of research. The code includes provisions for ensuring that coercion is avoided and informed consent is obtained. It also requires researchers to minimize suffering, harm, and injury (Nuremberg Code 1949). The World Medical Association's Helsinki Declaration contains similar provisions for protecting the rights and welfare of human subjects (World Medical Association 2008).

Another goal of human research rules is to promote social justice. Again, history teaches us that justice has been an important concern in the development of ethics documents and guidelines, such as the Belmont Report. The Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, a body that was created when the National Research Act (Pub. Law 93–348) was signed into law in 1974. The National Research Act was a direct response to Congressional hearings on abuses in research conducted in the United States, such as the Tuskegee Syphilis Study. Though the drafters of the Belmont Report were concerned about protecting human rights and welfare, they also drew attention to the importance of equitable subject selection and a fair distribution of the benefits and burdens of research (National Commission 1979). The Council of the International Organizations of Medical Sciences (CIOMS) Ethical Guidelines for Biomedical Research Involving Human Subjects also include statements concerning justice, equitable subject selection, and the fair distribution of the benefits and burdens of research (CIOMS 2002).

A third goal of rules for protecting human subjects in research is to produce results that benefit society. Some of the social benefits of research may include the development of new treatments or therapies, promotion of public health, and improvements in our understanding of biomedical sciences such as physiology, psychology, pathology, cytology, genetics, and anatomy. The Nuremberg Code includes a statement that research should yield results for the good of society, and the Belmont Report includes a discussion of the social benefits of research (Nuremberg Code 1949; National Commission 1979). The CIOMS Guidelines also emphasize the importance of producing social benefits from research (CIOMS 2002).

A fourth goal of rules for protecting human subjects is to foster public trust in biomedical research. Though this goal is rarely mentioned explicitly in key policy documents, it is an implicit assumption that undergirds many of the rules, guidelines, and declarations related to research with human subjects. Without a high level of public trust, biomedical research cannot move forward. Public trust is essential to secure funding and institutional support for research and to recruit human subjects. Institutions will not want to spend money on research regarded as immoral or irresponsible, and individuals will not enroll in clinical trials if they do not believe that they will be treated ethically. The Tuskegee Syphilis Study, for example, had a detrimental effect on African Americans' trust in biomedicine and has undermined their willingness to participate in research (Shavers et al. 2000).

Many key policy documents have been drafted to help restore public trust in biomedical research in the wake of scandals or abuses. Congress passed the National Research Act and formed the National Commission to help restore public trust damaged by the Tuskegee Syphilis Study. A more recent example of taking action to restore public trust resulted from

Jesse Gelsinger's highly publicized death in a human gene therapy phase I study at the University of Pennsylvania in 1999, which led to a reexamination of oversight mechanisms and financial relationships in research involving human subjects. After the Gelsinger incident, several organizations, including the Food and Drug Administration, Department of Health and Human Services, and American Association of Medical Colleges, revised and strengthened their conflict of interest policies and guidelines. Research institutions, funding organizations, and professional associations also took steps to improve their review and oversight of research with human subjects (Shamoo and Resnik 2009).

One of the implications of adopting public trust as a goal is that some of the rules for human subjects may need to go above and beyond the ethical and legal safeguards that operate outside of the research setting, so that the public will be assured that investigators are taking special care to protect human subjects from harm or exploitation. There is evidence that many of the research rules do, indeed, offer human subjects more protection from harm or exploitation than they would have outside the research setting. For example, rules and guidelines pertaining to risk exposure in research are more protective than rules concerning risk exposure outside the research context (Miller and Wertheimer 2007). Adults in the United States are free to smoke cigarettes, consume large quantities of alcohol, skydive, and take other risks that they would not be allowed to take in research that offers no medical benefits in return. Parents are allowed to expose their children to risks, such as secondhand smoke or skiing, which would not be permitted in research that offers no medical benefits. Some of the rules discussed by Sachs, such as the right to withdraw from research without penalty or loss of benefits and prohibitions against undue financial inducements, also function as paternalistic restrictions on risk. Other rules discussed by Sachs, such as the requirement that research be responsive to community needs and the requirement that interventions developed in a study be made reasonably available to the host population, may help to counteract the public's fears that research is exploitative.

Thus, I agree with Sachs that we need to consider the policy objectives of rules designed to protect human subjects in research. One of the goals of developing these rules should be to foster public trust in research. Once we recognize public trust as an important policy objective, we may begin to understand why some of the rules pertaining to research with human subjects need to provide protections from harm or exploitation that go above and beyond those found outside the research setting.

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