U.S. Research Regulations: Do They Reflect the Views of the People They Claim to Protect?

In this issue, Cho and colleagues (1) suggest that the public's ideas about research ethics, particularly about informed consent for research on widely used medical practices, differ from the ideas reflected in federal regulations. This is not surprising. Federal regulations have been harshly criticized by many groups, including AIDS activists, consumer groups, professional societies, bioethicists, and leaders of the National Institutes of Health (2–6).

The current regulatory system for clinical research is cumbersome, creaking with age, and conceptually inadequate. It was created before desktop computers, smart phones, and the Internet. It relies on ambiguous interpretations of basic concepts, such as "risk," "research," and "respect for persons." Thus, it is no shock that the current system does not reflect the contemporary views of many Americans. Still, some defend it and warn that changes in the strict requirement for informed consent would place research participants at risk.

The most powerful argument in favor of strict requirements for informed consent is Kantian. By this argument, research participants are treated as a means to an end. Some may be harmed so that others may benefit. Consent is a safeguard; it ensures (in theory) that participation is voluntary and that participants are aware of the risks. Advocates of a strict requirement for consent fear that, without it, researchers' drive to create new scientific knowledge will cause them to tumble down a steep and slippery slope, where they will join the researchers responsible for Tuskegee, the human radiation experiments, and the Guatemala syphilis studies. Only the requirement to fully inform potential research participants can prevent this dreadful slide.

An equally powerful argument can be made against strict requirements for informed consent when studies are low-risk and cannot practically be done without a waiver of the consent requirement. We all want safe and effective health care. Such care requires good research, and some research is infeasible if fully informed consent is required. Because of these considerations, we do much research today without consent. We just do not call it "research." For example, to accept Medicare insurance coverage is to accept participation in research involving Medicare claims data. When accepting third-party insurance payment, one allows payers to analyze data on care patterns and outcomes. Hospitalized patients implicitly consent to the quality improvement studies and data analyses hospitals do to improve safety. Filling a prescription means becoming part of a pharmaceutical database. Why, then, are the data acquisition and analysis activities that take place in projects labeled as "research" believed to be so morally different from these other activities?

Our unique sensitivity to the activities that we call "research" arose as a reaction to studies in which participants were explicitly deceived or coerced. In such studies, the researchers had no intention of disclosing the risks and no hope of benefitting the participants. Instead, they used their medical authority to fool participants into thinking that the research was, in fact, medical treatment. Ramsey (7), in his critique of the Willowbrook hepatitis studies, directed his ire at such experiments because, in his view, the research interventions were not designed to benefit the patients. Guttentag (8) was explicit in stating that research was particularly problematic only in studies that were not designed with the goal of direct benefit for the patient. Katz (9) noted that "research and therapy, pursuit of knowledge and treatment, are not separate but intertwined" (9). These pioneers of research ethics recognized that research may often be beneficial and that, when it is, the process of seeking true informed consent must be subtle, nuanced, and flexible. Today, the process has become abstruse, legalistic, and rigid.

Cho and colleagues show that most people understand the tradeoffs and want something different. Given a choice between research with no consent or consent with no research, the vast majority choose the former. How, then, do we deal with the small minority who prefer the latter choice?

We face political and ethical conundra. Should policy be shaped by the preferences of the majority or the fears of the minority? In other areas of civil life, we seek a balance. We allow free speech, up to a point, but draw the line at hate speech or incitement. Where and how should we draw the line between the preferences of the majority about consent for research and the deeply felt values of a minority?

Research regulations should reflect the values and preferences of the persons who will be participating in and benefitting from clinical research. This should not be a radical suggestion but our current system clearly fails by these criteria. Research participants have little input into study questions, study design, data analysis, or publication of results. They do not get to shape the regulations that will allow or prohibit their participation in studies. Respect for persons, in this context, offers only the option to answer "yes" or "no" to a consent question that has been written by others.

Cho and colleagues challenge us to think of a better way. Autonomy should mean participatory engagement. Respect for persons should mean empowering them to develop the rules (10). It is time to ask whether a system in which the fundamental principle is "respect for persons" can continue to ignore the preferences of many of the persons it claims to respect.

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