Genomics Research and Human Subjects

Henry T. Greely

The ability to create vast amounts of genomic data and to correlate them with huge databases of medical records promises better understanding, and ultimately better treatment, of many common diseases. Fulfilling this promise will require more than dedicated researchers, fancy technologies, or even money—it will require the cooperation of tens of thousands of people as research subjects. But the human side of this work remains dangerously underdeveloped. In the United States and in many other countries great strides have been made in ensuring that research is safe for human subjects, but thus far, too little attention has been paid to whether it is fair to those subjects. On that question, a social and legal consensus is lacking. Both research subjects and researchers desperately need one.

These questions of fairness are not hypothetical nor do they have clear, generally accepted answers. They have emerged not only in laboratories around the world but in paralyzing disputes over previously collected tissue samples and in stories, now spread quickly around the world, about "stolen spleens" and "patented tribes." Some of them are raised in striking fashion by the current proposal by the government of Iceland and DeCode Genetics to create a clinical database on the Icelandic population for research use. The questions are not unique to genomic research, but they do take on greater significance there. Rightly or wrongly, many people are convinced that genes are special, that they contain and reveal a person's, or a people's, essence, which has enormous value, spiritual and commercial. This exaggerated emphasis on the importance of individual genetic variation makes human genomic research particularly sensitive.

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Although the use of previously collected samples and data remains mired in controversy, it should be possible to create a clearer and better framework for research with newly gathered material. That framework will need to treat possible research subjects fairly and candidly, allowing them to decide whether, and how, to participate with as full an understanding as possible of all the consequences. As far as possible, people should be told what kinds of uses, present and future, may be made of their materials and by whom. They should have a choice as to what kinds of information about the research they wish to receive. When preexisting groups of people are likely to be affected by the research, the groups should be consulted about the research. And potential research subjects should be told about the possible commercial value of the research or the possible embodiment of the work (or their tissues) as intellectual property. A participant's altruistic feelings might well change depending on the extent to which someone else stands to profit from the research.

In sum, the people whose genetic and clinical data will be essential for the next phase of human genomics research need to be treated not merely as "subjects" but more as (somewhat limited) partners. Researchers must recognize that these people have interests beyond safety; ethicists must recognize that, when well informed, they have the right to participate even in broadly defined research. The goal of this approach is not to prevent research but to prevent research subjects from feeling cheated, powerless, misled, or betrayed.

More attention should be paid to research subjects' wishes because it is the right thing to do, but that attention does have a more tangible value for science. In its absence, scientifically and medically valuable research may be stalled by an increase in politics, in litigation, or, most damningly, in mistrust. The still-strong effects of the Tuskegee study on African-Americans' views of medical research provide one frightening precedent. This new research is too promising to risk a similar fate. A clear, generally accepted, and fair framework for the relationship with research subjects might impose some short-term costs on researchers, but its absence is both dangerous to researchers and unfair to the people who offer themselves as human subjects.

H. T. Greely is professor of law and codirector of the Program in Genomics, Ethics, and Society at Stanford University, Stanford Law School, 559 Nathan Abbott Way, Stanford, CA 94305–8610, USA. E-mail: greely@leland.stanford.edu

CONTACT *SCIENCE*

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