To the Barricades!

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To the Barricades!

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Mark Rothstein (2010) argues that current American regulations concerning deidentified research data and biological samples, as well as common practice by researchers and researcher overseers, are unethical, as well as quite possibly against the best long-term interests of biomedical research. He’s right. Rothstein urges that, as a consequence,

A detailed process of public engagement, pilot projects, and careful study is needed before any type of regulatory coverage should be extended to deidentified health information and biological specimens. In the interim, responsible researchers should consider whether, in the context of their particular research, additional measures are needed to protect deidentified health information and biological specimens and demonstrate respect for the individuals from whom the information and specimens were obtained. (3)

He’s wrong. What we need is not a “detailed process” but a revolt, if not a revolution.

The problems Rothstein points out in the research use of deidentified information and biological samples are real, but they are deeper, broader, and more serious than he argues in this paper.

He identifies six risks and one ethical problem. The risks are
1. The unregulated process of deidentifying data and materials
2. The problem of possible reidentification
3. Group harms
4. Objectionable uses
5. Commercial exploitation
6. Undermining trust (hence participation in and support for research).

The problem is that our treatment of deidentified information and samples completely ignores research participants’ autonomy—their rights to decide whether they want to take part in any given research project.

The article discusses these issues when they arise from research with deidentified information and samples. And, apparently, although this is not entirely clear from the article, Rothstein is focusing on situations where data and samples collected for non-research uses (presumably clinical) are first used for research only after they are deidentified. But this field of vision is too narrow. The issues he raises are true not only with newly deidentified data but also with the more common situation where data collected in some kind of identifiable form for one specific research project are then deidentified and used, or made available for use, in other projects with other goals. Furthermore, all of the risks except the first (the process of deidentification) also apply to “anonymous” data and samples, those collected without any personal identifying information.

Although the research system’s treatment of deidentified or anonymous research information and samples is egregious, this is not the only major problem with how we currently regulate human subjects research. Researchers need to pay more attention in many ways to the interests and wishes of the people who donate the information and samples essential for the researchers’ work (and careers).

Researchers need to use the information and samples only for purposes to which the research participants have agreed, or to which some independent party thinks they would agree. Instead, they use inconspicuous broad language in consents—to study diabetes “and other conditions”—to justify using samples for any kind of research, whether the research participant would like it, hate it, or not have a clue about its meaning.

Researchers need to share the information and samples with other researchers only when and as permitted by the research participants. Instead, they use similarly vague language to justify depositing personal health information, family histories, genotypes, and even gene sequences into databases open broadly to researchers—or perhaps to anyone with Internet access.

Researchers need to commit themselves to offer to return to the research participants important information the researchers find out about them. Sometimes this information will involve the hypothesis of the research (that a particular genetic variation in fact causes a certain disease); more often, the information will be “incidental findings” about generally known risks uncovered in a particular research participant through a research genome analysis or brain scan. Researchers should be eager to deliver individually important findings from their research to research participants—at least when the findings involve critical medical information, and perhaps other information as well. They should be eager to repay research participants for their help by giving back to them crucial findings.

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Instead, many if not most research protocols promise not to return any information to the participants, no matter how important.

These are not outrageous demands — on the contrary, it is outrageous that these rights are almost universally denied to the people whose gifts of information and tissue make biomedical research possible. This state of affairs continues because it is blessed by the interpreters of research regulations—themselves thoroughly conflicted because deeply embedded in the powerful research enterprise—and, I suspect, because most research participants do not have a clue that it exists. Instead, they believe that researchers must already be doing these things. The greater the trust, the greater the disillusionment on discovery.

These are not new concerns. I date them to the December 1995 Journal of the American Medical Association article by Ellen Wright Clayton on the use of stored tissue samples (Clayton 1995); I have written about them myself many times (North American Regional Committee 1997; Greely 1998; 1999; 2000; 2001; 2007; 2010). Others, some cited by Rothstein, have also taken on one or more of these problems. The resulting silence, in terms of changes to research regulation, has been deafening.

Rothstein is right that researchers, desperate for additional data and samples (in part because of the disappointing health results, to date, of the Human Genome Project and other expensive research), are constantly trying to use more and more information and samples, without the costly inconvenience of asking permission from the donors of that information and those samples. But he is wrong in advising that we lobby for a long and detailed process to consider revisions to the treatment of deidentified data, while politely requesting researchers to think a little more about the interests of research participants. Useful change will only come if those who control human subjects research in the United States, primarily the Department of Health and Human Services (HHS), are forced to change.

What we need is a revolution—or at least a little hell-raising. And that may not be impossible. The blindfolds may be slipping from the eyes of research participants, and of the general public. A best-selling book about Henrietta Lacks and her family has stirred up interest (Skloot 2009). The recent settlement of the Havasupai case—and its coverage in an above-the-fold first-page story in the New York Times—will have opened some eyes (Harmon 2010). Texas just destroyed more than 5 milliononaldal DNA samples as a result of the settlement of a lawsuit contesting research use of these samples, taken from newborns without their parents’ consent, for any purpose. A similar suit is on appeal in Minnesota. As more and more people find out what can be done—or is being done—with their health information, their family histories, and their DNA, the pressure for change should grow.

If we want to decry inappropriate research practices in academic articles, we can continue until, and well past, our retirements. If we want to see them changed, we need to push for change—through useful academic articles, like Rothstein’s, but also through publishing op-ed articles, making fiery speeches, encouraging the introduction of legislation and the holding of legislative hearings, and supporting appropriate litigation. Yes, any progress will probably require long and detailed assessments of what changes should be made, but those talks will never start unless they are forced to start. Nothing has changed in the last 15 years except the even greater invasion of the legitimate interests and rights of those who, voluntarily or not, knowingly or not, have become part of biomedical research.

We surely will not see barricades in the streets around HHS headquarters on this issue. But we need their equivalent—not just academic dissections of the status quo, but a movement to change it. Who’s with me?

REFERENCES


