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Gift Giving to Biobanks

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We agree with Mark Rothstein's goal of giving tissue donors control over their donated tissues. But we think using the research model as the basis for attaining this goal, while widely employed and accepted, should be abandoned.

The research regulations were originally adopted to deal with interventions on living human beings, not on the tissue of human beings. The Nuremberg Code (a reaction to concentration camp experiments), the Willowbrook experiment, the Tuskegee syphilis experiment, and the other examples of the abuse of research subjects that provided the rationale for regulating research on human subjects clearly had nothing to do with research on their tissues. The regulations were directed at protecting the safety and welfare of the living human beings who are being intervened upon by researchers.

Moreover, most of the concern over tissue collection has little, if anything, to do with research. For example, the creation of a tissue repository, regardless of the Office for Human Research Protections (OHRP 1997) position and guidance, is not research at all. There is no hypothesis, no methodology, no statistical design, and so forth. It is a mere warehouse of tissues, and all the tissue could be discarded without anyone ever doing anything to them resembling research. Nonetheless, the fact that tissue banking per se is not research doesn't mean that there should be no rules for the donation of tissue to tissue banks. But rules for the donation of tissue to banks should not be dictated by inapt research regulations.

One of the concerns that Rothstein addresses is the stigmatization of a group as a result of tissue analysis. As an example of "group-based harm" he discusses the 2010 Havasupai Indian Tribe settlement with Arizona State University. Apparently, Rothstein and the tribe believe it was "harmed" as a result of the DNA analysis and publication of results. Analysis of tissue samples apparently demonstrated inbreeding among tribal members and a higher incidence of schizophrenia than the rest of the population and established that the Havasupais were not created in the canyon in which they now live, which belief is an important part of their lore and provides them with certain rights under federal law. Needless to say, these conclusions about the

Havasupais could be readily determined from nongenetic sources. If there is an isolated tribe with 650 members, and its members reproduce, then a conclusion about inbreeding can be made without resort to DNA analysis. Similarly, determining the levels of schizophrenia within a group is an epidemiologic task rather than a genetic one. Generalized characteristics of a group (whether one labels them as stigmatizing or not) can be determined (and generally are) by nongenetic means. This is largely because stigma is not derived from genotypes or any other factual information but from mere bigotry, which is neither created nor resolved by facts.

The concern about group stigmatization also illustrates why the research model does not address biobanking practices in a useful way. Institutional review boards (IRBs) are prohibited from even considering the issue of group stigmatization or other positive or negative social impacts on groups when reviewing a research proposal. The regulations state,

The IRB should not consider possible *long-range effects of applying knowledge* gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (45 CFR §46.111(2), emphasis added)

This provision makes perfect sense in context. The research rules are designed to protect individual research subjects from the effects of interventions, and not the groups from which they come.

As for deidentification, once again the research rules run contrary to the Rothstein analysis. The rules rightly draw a distinction between identifiable and nonidentifiable data about individuals, and presume that there should be a difference in how such data are treated (45 CFR 46.101(b)(4)). A test tube of blood in a laboratory with no markings on it all cannot be used to derive information about an individual and therefore cannot be considered research on a human subject. Rothstein discusses his concern that the creation of more powerful techniques has made it possible to reidentify specimens that could not have been identified in the past. There are two answers to this concern. The first is that no one cares about the DNA of most of us enough to go through

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cumbersome process of reidentification. If someone wants to know whether an individual suffers from schizophrenia, the last place they would likely look is at a person's DNA sample. While this reality puts the problem of access to samples in some perspective, it does not resolve the issue. Rothstein himself has presented a reasonable solution, which is to make the reidentification of deidentified samples a crime. This is the common method by which we deter people from doing things we don't want them to do. There is no reason to believe that criminalizing such behavior would be less effective than other approaches to protecting deidentified tissue or other medical information.

Given the shortcomings of previous research protections-based approaches, we suggest that it is time to take a new approach to protecting tissue donors. This approach would be based on the notion of property rights in tissue (Glantz, Roche, and Annas 2008). This approach recognizes that tissue donation is not the same as consent to research, and may not involve research at all. Rather it establishes that tissue donation is the making of a gift. Perhaps the most destructive aspect of the *Moore v. Regents* (1990) case is its conclusion that everyone in the world could own a person's tissue except the person from whom it came. The *Moore* analysis of this issue is shallow and unconvincing.

By treating tissue donation as a gift of property, we have solid and well-developed legal and ethical precedents to call upon in our analysis. We propose that individuals from whom tissue is taken for any purpose other than the medical treatment of the individual must explicitly make a gift to the person who wishes to use it for any other purpose. This gift would be given outside of the informed consent process for research. It is now quite common for research consent forms to simply require a potential subject to mark a checkbox authorizing sending tissue to repository for some unknown future research. Making this part of the research informed consent process confuses everyone as to what the donor is actually doing, and leads to unending conflicts about the types of research that can be conducted on the samples without "reconsent."

As with other gifts, the donor could decide to make an unconditional or conditional gift of the tissue. An unconditional gift would be to simply give the tissue to someone to do with whatever they wish. It would be like giving a thousand-dollar donation to a research center to do with it as the research center pleases. Or the gift of tissue could be a conditional one, permitting the sample to be used for cancer research, but nothing else—just as I could specify this limited use when I give my thousand-dollar donation to the same research center. Apparently the Havasupai tribal members did not think they had made a gift at all. Rather, the Havasupai apparently believed that their tissue donations were conditional in that they were to be used to help

researchers find a solution to the excess diabetes that afflicted tribal members. In other words, it appeared to be a quid pro quo to tribal members, rather than an outright gift. And while there would be every reason to believe that the boilerplate provision about allowing tissue samples to be broadly used was in whatever research consent form they signed, it is a poor way for an institution to argue that it received a bona fide gift of tissue and a very poor way of informing the donors that have actually made such an unconditional gift.

Under the gift model, a donation document would be similar to the one currently used by development offices, rather than one used by human research subject offices. The conditions set by a donor can, of course, be so burdensome that the institution may choose not to accept the gift of tissue from a particular donor. If the donor's conditions were that the tissue could be used for breast cancer research and brain cancer research, but no other cancer research, and for congestive heart failure but no other heart conditions, it would essentially be impossible to keep track of what the sample could be lawfully used for. This doesn't mean that the donor should not be able to set conditions; it simply means that institutions will need to evaluate the conditions to determine whether they wish to accept the gift.

If this approach had been taken with the Havasupai tribal members, it would have been clear to them and the university what the transfer of property meant. By not confusing the research that was to be done on diabetes, which the Havasupai apparently desired, with the unconditional gift that the Arizona State University thought it had received from the donors, the confusion would likely have been avoided. People who aren't lawyers, ethicists, or researchers are much more likely to understand the language of gifts than the language of DNA research. For these reasons, we suggest moving away from the autonomy/research model in addressing biobanking, and adopting the gift of property model. ■

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