A Breach of Confidentiality

The research I was doing involved working with tissue samples from a large number of patient-donors that were collected over the course of 20 years. IRB approval for acquiring specimens and protocols were obtained according to institutional and federal government guidelines and the study proceeded without incident. Indeed, the lab published several important papers in the field and, of course, maintained the privacy and confidentiality of all donors.

But one day when I was well into my work, I was nonchalantly informed by one of the principal investigators in the lab of the identity of one of the donors of our specimens. The donor was a highly visible, nationally known celebrity.

I never found out how this investigator came to know this tissue donor's identity. To my knowledge, the only information that the laboratory staff had was their donor's age, sex, and race. In fact, none of the laboratory's documentation described any donor in any specific terms. Nevertheless, and as result of this revelation, I was faced with the problem of deciding whether or not to continue to conduct research using cells derived from this individual. This was especially problematic for me because this donor's cells had been very useful to me, yielding promising and exciting data up to that point.

Ultimately, I decided that it would be inappropriate for me to continue conducting experiments using cultures from cells derived from this person. But I wonder if I was being "too ethical." Was I?

Expert Opinion

Before 1990, stored tissue was routinely used for research without any consent from the tissue donor. Two events changed that. The Centers for Disease Control wished to do genetics research on its extensive sample collection. Realizing that genetic research might be sensitive for numerous reasons, in 1994 the CDC seated the Clayton Consensus Panel to give ethical guidance. This panel devoted much discussion to using sample banks obtained without consent; but it also recommended that henceforth, consent should be sought before samples are banked or used for research.[1]

At approximately the same time, John Moore sued the Regents of the University of California for breach of fiduciary duty. In 1979, a UC researcher arranged for research on Mr. Moore's tissue obtained from a splenectomy as part of his treatment for hairy cell leukemia, without disclosure to the patient. For the next seven years, the patient traveled from Seattle to UCLA to give blood, blood serum, skin, bone marrow aspirate and sperm that were deemed *"necessary and required for his health and well being."* In its ruling, the Court recognized that the potential market of lymphokines developed from Mr. Moore's tissue was about $3 billion, but did <u>not</u> recognize his right to this money. It did rule that the physicians had breached their fiduciary duty to the patient and had not obtained proper informed consent. (*Moore v. Regents of the University of California,* 793-P.2d 479 (Cal. 1990).

These two rulings, one ethical and one legal, established the standard requiring informed consent for research on human tissue. There are several ethically important categories of research tissue:

- totally anonymized samples that can no longer be linked to the donor;
- unlinked samples that are sent to investigators without codes or identifiers, though they are linked to identifiers in the bank, so that they are anonymous for this investigator;
- coded samples that are linked to the donor by codes;
- identified samples.

In the above case, since it was possible for the Principal Investigator (PI) to identify the donor—though the student researcher only knew the donor's age, race and sex—we can assume the samples were either unlinked or coded with the code unavailable to the student researcher.[2] If the IRB at this institution was following standard procedures for unlinked or coded samples, it would only have approved a protocol that specified that the researchers would know the donor's age, race, and sex; not his or her identity. If this is in fact what the protocol governing this research stated, this revelation of identity must be the result of a protocol violation (at a minimum).

More importantly, we must consider whether this revelation of identity harmed the donor and contradicted his/her informed consent for research use of his/her tissue, if there was consent. Since the tissue that this student is using in his or her research was obtained in the last 20 years, it might have been obtained without consent given that the standard regarding consent changed in the middle '90's. Most ethical statements allowed use of pre-consent archived samples if anonymized. If coded, many ethical statements required obtaining consent.[2, p.100] Since this sample was clearly not anonymized, consent was probably obtained from the donor. That consent, assuming it was standard, would have assured the donor that his/her identity would be protected and not released to researchers. Here is a standard statement:

> We would like to give the Researchers information – such as whether you are male or female, your age, your race and information about health related issues, including information such as your history of smoking, current medical or surgical diagnosis or previous medical treatments. Information that identifies you, like your name or address, will not be given and will remain confidential. (Emory Front Door consent).[3]

If the consent was standard, the PI has now clearly acted in contradiction to what the protocol promised the donor. The principle of research ethics that has been the bedrock principle since the Nuremberg Code—to only do research with consent—has been broken. The student rightly identifies that she is in an ethical pickle.

However, we believe the question the student asks herself is not the right one. She asks: should I continue using this tissue? It is no wonder she is perplexed by this question, because as the investigator, she is not the right one to answer that question. We have found through decades of unfortunate experiences, that the investigator alone should not be expected to answer difficult research ethics questions. Instead, in the United

States, we have developed patient and investigator protection systems, with entities removed from the research and presumably not biased by their participation in the research, who are charged with making these important ethical decisions.

The objective in this case would be to engage an unbiased body in serious ethical reflection about how best to protect this donor, as well as how to go forward with what may be research that is beneficial to many before we could decide this. Certainly, the institution's IRB would be clearly involved. *The student has witnessed both a protocol and a consent violation, and the IRB must be notified of both*. Of course, we do not underestimate how difficult this is for a student when the violator is his or her PI. But many institutions have ombudsmen or ethics consult services that can help a student navigate this difficult situation. But only an unbiased group, like an IRB, should make the determination of whether or not these ethically compromised samples can be used.

More important, the IRB or the Office of Research Compliance can investigate the system failure that allowed these violations to occur. If the PI knows this sample's donor's identity, the system in place to protect confidentiality is obviously flawed and must be corrected before any tissue research can continue. Otherwise, the informed consent that is so painstakingly obtained for samples is undermined by a system that disrespects the informed consent's parameters. All research from this tissue bank is potentially in jeopardy of being conducted unethically. The student has uncovered a serious organizational ethics problem. It is not the student's responsibility to solve this problem, but it is the student's responsibility to notify the entity in the organization that has the power and expertise to solve it.

So, should the student continue to use the sample? One resolutional strategy would be to engage an unbiased body in serious ethical reflection about how best to protect this donor, as well as how to go forward with what may be research that is beneficial to many before we could decide this. Nevertheless, we believe it is very unlikely that this deliberation will conclude that the student can proceed since the student now knows this donor's identity and will be finding out personal information about the donor's sample. It is very likely that the student will be unable to disassociate from a person whose identity she knows (and even if she is psychological able to do this, other students might not). Having this knowledge without consent will be an assault on the donor's privacy. But, if the research is important enough, it may be possible to transfer this line of research to another investigator in such a way that the donor's identity is once again concealed.

A provocative approach that, as far as we know is untried, is to contact the donor and disclose the breach. (This would not be disanalogous to informing a patient who has experienced a medical error about the event.) Rather than make a unilateral institutional decision to have the student or someone else use the sample or not, the sensibilities of the donor can be ascertained with, of course, an apology issuing from the institution. Now, such a disclosure opens the possibility that the donor might sue the institution for breaching confidentiality, but for the suit to succeed, the donor would

have to show that the confidentiality breach was so injurious to him or her—e.g., seriously compromised his or her earning capacity or resulted in physical illness—that asking for compensable damages would seem reasonable.

In any event, this incident certainly deserves to be investigated for the reasons mentioned although anyone can appreciate the degree of moral courage that would be required of the dilemma contributor to start the investigational ball rolling.

References:

1. Clayton EW, Steinberg KK, Khoury MJ et al. Informed Consent for Genetic Research on Stored Tissue Samples. JAMA, 1995; 274(22): 1786-1792.
2. National Bioethics Advisory Commission. Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Volume 1. Rockville Maryland, 1999, p. 58.
3. http://www.emoryhealthcare.org/departments/breasthealth/Breast_Research.html.