A Breach of Confidentiality: A Tissue Donor Identified

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Category: Confidentiality

<u>Ethical Dilemma</u>

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. The protocols for acquiring specimens were approved by the IRB according to institutional and federal guidelines and the study proceeded without incident. Indeed, the lab published several important papers in the field and 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 the donor's age, sex, race, and de-identified medical history. In fact, none of the laboratory's documentation included any protected health information (PHI) since all were coded. 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 my work, 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

Prior to 1990, stored tissue was routinely used for research without obtaining any consent of the tissue donor. Two events changed that. The Centers for Disease Control (CDC) 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 deliberated about the use of specimens that were obtained without consent and ultimately recommended that henceforth, consent should be sought before samples are banked or used for research.[1] At approximately the same time, Mr. Moore sued the Regents of the University of California for breach of fiduciary duty. In 1979, a University of California researcher arranged for research on Mr. Moore's tissue obtained from a splenectomy as part of his treatment for hairy cell leukemia. The researcher did not inform Mr. Moore about the research. For the next seven years, Mr. Moore traveled from Seattle to UCLA to give blood, blood serum, skin, bone marrow aspirate and sperm-all taken as "necessary and required for his health and well being." In its landmark decision, the Supreme Court of California recognized that the potential market of lymphokines developed from Mr. Moore's tissue was valued at over $3.01 billion.[2] While the Court did not recognize

Mr. Moore's right to share in the profits of the products derived from his cells, they did rule that the physician had breached his fiduciary duty to the patient since he had not obtained proper informed consent.[3] These two rulings, one legal and one ethical, established the standard of requiring informed consent for research on human tissue.

There are several categories of ethical importance research tissue may fall in: (1) Unlinked (irreversibly anonymized) samples that can no longer be linked to the donor; (2) coded samples that are linked to the donor by codes but only the tissue bank has access to the identifiers (reversibly anonymized); and (3) identified samples.[4] IRBs can release identifiers if the research cannot be conducted without them but the student researcher knew that their protocol had requested coded samples, with only the tissue bank having access to identifiers.[5] A breach of protocol had occurred since the PI knew the donor's identity.

Additionally, 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 her research was obtained in the last 20 years, it is likely the sample was consented for research as a result of mid 90's reforms that set standards regarding informed consent. That consent, assuming it was standard, would have assured the donor that his/her identity would be protected and not known to researchers. This is an example of 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).

If the consent for this research was standard, the PI has clearly contradicted a promise to the donor made in the consent. The bedrock principle of research ethics that has been in place since the Nuremberg Code, namely to only conduct research with patient consent, has been broken. The student rightly identifies that she is in an ethical conundrum.

The question the student asks herself, however, is not the right one. She asks: should I continue using this tissue? It is no wonder she is perplexed by this question, for as an investigator deeply involved in the research, she is not the right one to determine the proper response. We have found through decades of unfortunate experiences that the investigator alone should not be expected to answer difficult research ethics questions pertaining to their work. Instead, in the United States, we have developed patient and investigator protection systems. These are run by entities removed from and presumably not biased by their participation in the research, charged with making these important ethical decisions. In this case, the entity that should make the decision is the respective institution's Institutional Review Board (IRB). The student may have witnessed both a protocol and consent violation, and the IRB must be notified of both. We do not underestimate how difficult this is for a student when

the violator is her PI. Many institutions have ombudsmen or ethics consult services that can help a student navigate this difficult situation and navigate means of reporting potential violations. Here, only an unbiased group, like an IRB, should make the final determination of whether or not the identified sample can be used.

In addition to investigating the specific violation, the IRB can investigate the system failure and culture that allowed for this violation to occur. If the PI knows this sample donor's identity, the system in place to protect confidentiality appears to be flawed. This system of protecting confidentiality must be corrected before any tissue research can continue. A flawed system of respecting the parameters of confidentiality undermines the informed consent that is so painstakingly obtained for samples. Moreover, the student has uncovered a serious organizational ethics problem. Though it is not the student's responsibility to solve this problem, it is their responsibility to notify the entity within the organization that has the power and expertise to address this problematic practice.

In sum, should the student use the sample? The ultimate decision should be made by unbiased body who, after serious ethical reflection, decides how best to protect this donor as well as go forward with what may be research that is impactful to many. It is very unlikely that this deliberation will conclude that the student can proceed: with knowledge of the donor's identity and personal information about the donor's sample, the student will be unable to disassociate the personal information from the identified donor. Having this knowledge without consent and continuing work will be an assault on the donor's privacy. If, however, 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 careful weighing of the risks to the donor and the benefits to humanity must be accomplished and ultimately guided by a careful IRB review.

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[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] Moore v. Regents of the University of California, Cal., (1990) 793-P.2d 479.

[3] Ibid.

[4] Elger BS, Caplan AL. Consent and anonymization in research involving biobanks: differing terms and norms present serious barriers to an international framework. *EMBO Rep*. 2006;7(7):661-666. doi:10.1038/sj.embor.7400740

[5] http://www.irb.emory.edu/forms/Waivers/Waver_of_Consent.html