

“The Claims of Biospecimen Donors to Credit and Compensation”
Presented by Dave Wendler, Ph.D.

Online Questions from Registrants

On October 26, 2020, Dr. David Wendler conducted an ENRICH Forum webinar titled “The Claims of Biospecimen Donors to Credit and Compensation.” Current practice maintains that biospecimen donors do not have a claim to compensation. This practice is reflected in consent forms which disclose that donors will not receive a share of any profits derived from research using their samples. Dr. Wendler argued that this practice is mistaken, and that in some cases, biospecimen donors merit compensation. Numerous questions arose during this presentation which could not all be addressed during the allotted time. Dr. Wendler provided responses to the following questions which could not be answered during the recorded presentation.

1. *“What/who were the four groups that proposed a metric for compensation in the wake of the [Moore](#) case (establishing under CA law that patients do not have a property interest in their excised biospecimens used for medical research)?”*

Bovenberg J. [Whose tissue is it anyway?](#) *Nat. Biotechnol.* 2005; 23: 929-933.

Harrison C.H. [Neither Moore nor the market: alternative models for compensating contributors of human tissue.](#) *Am. J. Law Med.* 2002; 28: 77-105.

Winickoff D.E., Winickoff R.N. [The charitable trust as a model for genomic biobanks.](#) *N. Engl. J. Med.* 2003; 349: 1180-1184.

Merz J.F. et al. [Protecting subjects’ interests in genetics research.](#) *Am. J. Hum. Genet.* 2002; 70: 965-971.

They are also cited in the paper which was the basis for my talk:

Wendler D.S. [The Claims of Biospecimen Donors to Credit and Compensation.](#) *Trends Genet* 2020 Sep;36(9):630-632. doi: 10.1016/j.tig.2020.06.005. Epub 2020 Jul 10.

2. *“In your out-of-the-blue idea, having the idea isn’t the end. The person with the idea must develop it and make the case that it is useful. If they don’t, they get no credit for the idea. A donor of useful cells ends with the “idea” - they don’t do the work afterwards to show the cells are useful. How do the donors differ from computer tech in your authorship example?”*

I agree that having the idea isn’t the end, but my thought was that it’s a vital beginning. Imagine you come up with the idea for DNA as a double helix and you tell it to your geneticist friends who develop it into a full account of the structure and function of DNA. There is obviously a lot you didn’t do to translate the idea into profitable products. But you did contribute to the valuable

properties of products that are based on your idea. Typically, computer techs don't have that kind of impact on the products of research.

3. *"There seems to be little incentive to reimburse patients for their contributed biospecimens when their material can be used anyway through de-identification of the material. Do you think changes to guidance from the Common Rule might change whether patients are compensated?"*

Great question. I don't know, but thinking about ways to help bring about what strikes me as a fairer system is a great idea. One of the challenges here is that the point of de-identification is to make it difficult to identify the sources of samples. But, in many cases at least, this is done through coding rather than complete anonymization (assuming that's even possible anymore) which allows the holders of the code to identify the donors.

4. *"Is a small thank-you gift, maybe \$25-300 USD, considered compensation?"*

It is, although typically it is considered compensation for the effort of participating, not for any contribution to the final product.

5. *"In our current system the largest pie of the profit goes to people who contribute money to the company. Not to people who provide the intellectual contribution. Is this relevant to your argument?"*

Very relevant. It shows that contributing to the valuable properties isn't the only way to merit compensation. It also raises difficult questions about how to compare and balance financial contributions with substantive ones. But, the claim that donors should be compensated in some cases does not introduce this challenge. It already has to be addressed when we consider how to compensate investigators versus investors.

6. *"Whose responsibility is it to determine what benefits are due to which party and how can that be enforced?"*

I think it should be the groups and institutions that make and distribute the money. Or, put another way, whoever determines currently when and how investigators are compensated should do this as well.

7. *"How does this apply to EMR data - contributed or sold by hospitals?"*

Good question. I am not 100% sure. We would need to consider to what extent individuals from whom we collect data make contributions to the properties which make the final products valuable. My guess is that, in most cases, they would qualify as a kind of "raw materials" contribution that I mentioned, which suggests that they would not merit compensation on these grounds.

8. *“Can you discuss the ethical issues involved when people volunteer for riskier research with the potential for higher monetary rewards?”*

This is an important issue. In general, there are at least two reasons to offer compensation to research participants. First, compensation is offered for the burdens and risks of participation. There is a rich literature on the ethics of paying for risks and burdens. Many are opposed to it, but not all. For the latter, you might be interested in looking at the work of Alan Wertheimer. Second, compensation is offered for contributing to the valuable properties of the final product, which I discussed.

Viewer Comments

The 'positive' or 'valuable' samples may not even be valuable unless they have 'negative' or 'null' samples to compare to, which is an argument to compensate all donors; they should at least get a raised minimum wage!!!

I work for a brain bank. I think that it is only when the donor (or their next of kin) has some awareness of how their tissue will be used that it is feasible to provide compensation. The valuable products might occur decades from now, and the donors certainly had no idea of how their samples contributed to the final product.....

If specimens like the HeLa cells are instrumental for any research to be advanced, the donor should be compensated. The researcher would have to buy mice to do the research on, so the raw materials should be compensated. The donor can decline.

One of the goals is to encourage patients to agree to donate their specimens. We should find a way to acknowledge their contribution. Without these samples we can't do research