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Broad versus Blanket Consent for Research with Human Biological Samples

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In a recent article, Tom Tomlinson argues, in effect, that current protection of research participants is based on an overly narrow conception of their interests ("Respecting Donors to Biobank Research," January–February 2013). While it is commonly said that protection of research participants should cover all risks, protections tend to focus on participants' welfare interests. This approach ignores the fact that research participants' nonwelfare interests can be set back by the studies to which they contribute. Individuals who contribute biological samples may be harmed—their nonwelfare interests may be set back—if their samples are used for studies that conflict with their fundamental values.

Tomlinson argues that recognition of individuals' nonwelfare interests undermines the use of blanket consent for research with biological samples. To this extent, I agree with Tomlinson's argument,[1] despite his several suggestions that I endorse blanket consent. To clarify this confusion and to understand the debate over consent for research with human biological samples, we need to distinguish between broad and blanket consent. *Blanket consent* refers to a process by which individuals donate their samples without any restrictions. *Broad* (or what I have called "general") *consent* refers to a process by which individuals donate their samples for a broad range of future studies, subject to specified restrictions.

As Tomlinson points out, blanket consent ignores the fact that, absent any restrictions, samples might be used in future studies that conflict with individuals' fundamental values. One way to address this concern would be to require donors to consent to individual studies, at the time the studies are proposed. While this approach undoubtedly protects donors from contributing to studies they oppose, it seems excessive. It requires donors to be contacted repeatedly over time, often for studies that do not differ in material ways. Moreover, this approach would be costly and has the potential to undermine the value of research with biological samples, thus setting back donors' nonwelfare interests in contributing to valuable projects.

> Ethical research does not require a guarantee of no harm. It requires investigators to exercise due diligence.

Broad consent offers one way to address these concerns. Unlike blanket consent, broad consent permits specific limitations on the future use of samples. For example, if there are specific types of research known to conflict with donors' fundamental values, such as studies on human cloning, these could be precluded by the initial consent.

I have argued that broad consent should include a requirement that future studies may be conducted only when an independent body charged with protecting donors, such as an IRB, judges that the proposed research is ethical and poses no greater than minimal risk.[2] Because Tomlinson does not distinguish between broad and blanket consent, I can only speculate on his response to this approach. It appears that his primary objection—and possibly the reason he fails to distinguish between broad and blanket consent—is that broad consent, like blanket consent, does not allow donors to control the specific studies for which their samples are used. Instead, an independent body makes these decisions. In his words, donors have "no prospect of learning about, or controlling" how their samples are used after they give consent.

Based on this concern, Tomlinson concludes that investigators have obligations to make information about the future studies conducted with donors' samples available and, to the extent possible, to allow donors to withdraw their samples if they find those studies problematic. One might defend the claim that these measures are obligatory on the grounds that review by an independent body, even one charged with protecting donors, does not *guarantee* that donors' specimens will not be used for studies that conflict with their values. Even a well-meaning, expert, and experienced committee may fail to identify the fundamental values of some donors. Recognizing this possibility, we need to resist a kind of genetic or stored sample exceptionalism that affects much of the literature.

Ethical research, whether it involves subjects' bodies or their donated specimens, does not require a guarantee of no harm. Instead, it requires investigators to exercise due diligence in protecting subjects. What is required to discharge this obligation depends largely on the magnitude and likelihood of possible harms, the extent to which the endorsed measures would reduce these risks, and the costs of so reducing them. For example, one-to-one nursing coverage for all research subjects who undergo an invasive procedure would reduce the risks they face (compared to the standard practice of having one nurse care for several subjects). Nonetheless, investigators typically are not obligated to take such a step because the extent to which it would reduce the risks subjects face would not (we assume) justify the costs.

The steps Tomlinson endorses—informing donors of future projects and providing the opportunity to remove samples—would reduce the risks to donors compared to reliance on an IRB alone. However, this is not sufficient to conclude that these steps are obligatory. Here too, it depends on the magnitude and likelihood of the possible harms, the extent to which the endorsed measures would reduce these risks, and the costs of implementing the endorsed measures. When risks are minimal and the costs of additional steps clearly greater than minimal, we often rely on IRBs to protect research subjects. We allow them to approve research without any consent at all and to permit research involving deception despite the possibility that the approved research may conflict with subjects' fundamental values.

The present analysis suggests that drawing the distinction between broad and blanket consent is crucial to understanding the implications of Tomlinson's arguments. Specifically, his arguments provide important reasons to reject blanket consent, at least in most cases. In contrast, his arguments do not seem to provide any reason to question broad consent for

research with human biological samples. Instead, he provides further support for one way to supplement broad consent.

Briefly, broad consent might involve inviting individuals to donate samples with the stipulation that future studies may be conducted only when an independent person or committee charged with protecting donors finds that at least four conditions have been satisfied: the proposed research is valuable, the proposed research is ethical, the proposed research poses no greater than minimal risk, and there is no reason to think that the proposed research conflicts with donors' values.

Tomlinson and others recommend that this approach be supplemented, when feasible, by having the sample holders (including investigators, biobanks, and biorepositories) make available information on the studies conducted using the samples they hold and by allowing donors to withdraw their (unused) samples.[3] In the end, then, Tomlinson's arguments provide additional support for the claim that broad consent, appropriately implemented, provides a way to protect donors without unnecessarily blocking valuable research.

References

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