



Facilitating Autonomy With Broad Consent

Ryan Spellecy

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Open Peer Commentaries

Facilitating Autonomy With Broad Consent

Ryan Spellecy, Medical College of Wisconsin

Grady and colleagues (2015) have provided a welcome and needed contribution to the robust debate surrounding informed consent for novel forms of research, including research on banked biospecimens, that did not exist at the time the federal regulations and the Belmont Report were drafted. What is of particular importance, and laudable, is that they did not simply rest on the laurels of the regulations that would permit certain research on biospecimens without consent or review, but rather sought to follow the strongest ethical justification and empirical evidence to guide their proposal. I am supportive of their proposal, and in what follows, I wish to provide additional support, as well as to highlight a particularly challenging nonconsequentialist concern regarding the use of broad consent for banked biospecimens, and sketch a possible solution.

Grady and colleagues move forward the proposition of broad consent for research on banked biospecimens that does not provide full information to donors about future research because full information is simply not possible. We cannot know at the time of consent that discard tissue from an abdominal surgery next week will in 5 years be used in, for example, basic science cardiovascular research to better understand the role of certain stressors in microvasculature. We can, however, inform donors of “possible future uses of the samples and the processes of oversight that will be used to review specific studies” (Grady et al. 2015, 37). While this is not fully informed consent, it may be sufficient for most potential donors and thus meet our obligations to respect autonomy. As Thomas May and I have argued elsewhere, autonomy does not require full information, in the sense that an individual is not required to obtain every piece of relevant information in order to make an informed, autonomous decision (May and Spellecy 2006). Our values act as filters for what information is and is not relevant for an autonomous decision, and it is consistent with autonomy for an individual who is generally supportive of biomedical research to give broad consent to future use of discard tissue even if he or she does not know the exact nature of that future research. Depending upon an individual’s values, that individual may

simply not be concerned with the exact nature of the future research, but would be generally supportive of medical research, and thus the exact nature of the future research is not necessary for her to make an informed, autonomous decision to donate her biospecimen. As the authors note, certain controversial categories, such as human cloning, might be highlighted in the consent process so that someone who is generally supportive of biomedical research, but has moral objections to human cloning, can make an autonomous decision to donate tissue for future research that is consistent with his or her values that support biomedical research generally, yet oppose human cloning.

While a complete consent process that lists all possible future uses is not possible, as future research is not known at the time of consent, a consent process that is either highly detailed at the time of consent, or seeks additional consent each time a sample is used, may actually undermine the autonomy of the donor. As consent forms become longer and longer, they become less comprehensible. This led to the National Cancer Institute issuance of guidance to decrease the length of consent forms in order to increase both participation and comprehension in potential research subjects (NCI 1998). There is a tension between completeness and comprehensibility, in which as consent forms become more complete and contain more information, they ultimately become less comprehensible to subjects. This tension between completeness and comprehensibility can even rise to the level where they are mutually exclusive. As a result, I have elsewhere called for a transition away from the reliance upon written consent forms as the prime vehicle for the informed consent process (May, Craig, and Spellecy 2007). Shorter consent forms such as those utilized in broad consent proposals decrease comprehensiveness, and length, and thus may improve comprehensibility. In this light, the reliance on broad consent for biospecimen research is not only warranted, but by virtue of its shorter length may result in improved understanding (Rogers et al. 1998) and thus be a better means to facilitate informed, autonomous decisions that may be useful in other research settings as well.

Address correspondence to Ryan Spellecy, Center for the Study of Bioethics, Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, WI 53226, USA. E-mail: rspellc@mcw.edu

A concern remains though for nonconsequentialist concerns in broad consent. While much of the focus in Grady and colleagues' article is on risks and the prevention of harm, this attention to consequentialist concerns does not address nonconsequentialist concerns, such as the right of patients to decide whether or not to participate in research. As the authors note, "Individuals' nonwelfare interests are not set back simply when their samples are used for research that they may not have chosen. For example, if in the future donors' specimens are used for research that they would not have prioritized but otherwise would not object to, this does not seem bad for them" (Grady et al. 2015, 39). Rather, as the authors note, donors' nonwelfare interests are violated when their samples are used for research that violates their core values. It is worth clarifying that what makes the use of samples without specific consent for purposes that are not objectionable to the subject permissible is not that the use is not objectionable, but rather that broad consent has been granted by the subject. Using samples for research to which a subject would not object in the absence of any consent would still violate that subject's right to decide whether or not to participate in research. It is thus important that, as the authors note, those who object to certain controversial forms of research, as noted in the preceding, can decline to consent and their samples will not be used. This is an important improvement over our current regulatory system that allows research without any consent on certain biospecimens. For the subject who has consented to the use of his or her

biospecimen in future research via broad consent, given that full information is not necessary for an informed, autonomous choice, and may even undermine autonomy as discussed earlier, nonconsequentialist concerns surrounding respect for autonomy and rights are adequately addressed. ■

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Going Beyond the False Dichotomy of Broad or Specific Consent: A Meta-Perspective on Participant Choice in Research Using Human Tissue

Thomas Ploug, Aalborg University Copenhagen

Søren Holm, University of Manchester, University of Oslo, and Aalborg University

Christine Grady and colleagues (2015) have presented a clear and comprehensive case for broad consent as an adequate way of balancing society's interests against concerns for the individual when it comes to research using biospecimens. They argue that there strong reasons for requiring consent for this type for research, and that both empirical research and more general considerations support a model of broad consent in preference to models based on consent

that is more specific to the particular study. While we agree that there are strong reasons for requiring consent for collecting and conducting research on biological samples, in this comment we argue (1) that neither the relevant empirical studies nor general considerations favor broad consent, (2) that broad consent may fail to act in the interests both of research and of the individual and his/her autonomy, (3) that positing a choice between broad and

Address correspondence to Thomas Ploug, Aalborg University Copenhagen, Centre for Applied Ethics and Philosophy of Science, Department of Communication, A. C. Meyers Vænge 15, 2450 Copenhagen SV, Denmark. E-mail: ploug@hum.aau.dk