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Linking Broad Consent to Biobank Governance: Support from a Deliberative Public Engagement in California

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In “Broad Consent for Research with Biological Samples: Workshop Conclusions,” Grady and participants in an NIH-sponsored workshop endorse the practice of broad consent for biospecimen use, sanctioning the merits of an approach that allows unspecified future research with few restrictions. They recommend broad consent as ethically appropriate “when coupled with on-going oversight,” as well as downstream communication with donors, enforcement of standards, and evaluation. Workshop members conclude that an ethical system of biobank governance will require intensive input from potential donors—the lay public. We support the authors’ recommendations with one caveat: without a fully robust system of oversight, including adaptive governance informed by disinterested citizen stakeholders, broad consent runs the risk of becoming a ritualized “checkbox,” a simple (often electronic) authorization to be documented, but providing little protection of donor interests. Fleshing out the suggestions offered by Grady et al., we describe our efforts at the University of California (UC) to elicit citizen recommendations about biobank governance, including the development and implementation of broad consent linked to mandated public outreach and ongoing community guidance.

The EngageUC project is an NIH-funded effort to engage all California stakeholders in biobank research, including the public, scientists, and university officials (Garrett et al. 2015). Our public engagements were designed to elicit precisely the kinds of considered lay perspectives called for by Grady, et al. Informed by theories of deliberative democracy, we conducted intensive, four-day community engagements in northern and southern California, asking citizens for advice on UC policies for biobanking governance and the implementation of informed consent practices. We recruited deliberants in partnership with the methodologically rigorous California Health Interview Survey to obtain a representative sample of Californians from Los Angeles (LA) and San Francisco (SF) area counties (n = 26 and 25, respectively); sampling was designed to achieve diversity in income, education, sex, age, and race/ethnicity. In addition, the LA event accommodated Spanish-speakers through the use of simultaneous interpretation. Participants, who were compensated \$120 per day, reviewed a detailed briefing book and website (<http://ctsi.ucsf.edu/engage-uc>). Over the four days, participants heard presentations from scientists and experts in biobanking, biomedical research, and privacy, to whom they could also address questions; deliberated in small and large groups with the assistance of a professional facilitator; and debated and endorsed recommendations emerging from their discussions.

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Here we present a brief summary of the findings from these deliberations that complement the recommendations offered by Grady, et al, and we present insights that are relevant to implementing a sustainable and ethical system of broad consent, as they recommend. Along with our citizen deliberants, we strongly believe that adapting a system of broad consent demands robust downstream governance and stepped-up community education.

EngageUC deliberants expressed little support for choosing specifically how their samples or data would be used in future research, and high levels of support for broad consent. Additionally, deliberants in both northern and southern California showed strong support for an independent, multi-stakeholder body that would provide robust oversight of biorepositories and associated biomedical research. Also complementary to Grady, et al.'s recommendations of enforcement, evaluation and sanctions for ethical research practices, EngageUC deliberants identified monitoring and appropriate consequences for the improper handling or misuse of data and samples as a key component of ethical biobanking and research.

Additionally, EngageUC deliberants generated and affirmed specific recommendations that are relevant to the implementation of Grady et al.'s suggested system of broad consent—specifically the development of suitable consent forms and models for the oversight of future research uses of stored samples. In both LA and SF, lay deliberants emphasized the importance of creating consent forms that made content easy for potential donors to understand (e.g., using large fonts and clear and simple wording in the individual's preferred language); of the consent process being conducted by knowledgeable, trustworthy individuals with time for discussion; and of the consent process being conducted at a time of low stress for the potential donor. Regarding models of oversight, EngageUC deliberants strongly supported the involvement of multiple stakeholders, such as community members, scientists, medical professionals, and lawyers. Participants felt especially strongly that members of donor communities be meaningfully involved within these oversight bodies and that the full diversity of these communities ought to be represented when membership on boards is considered. Deliberants envisioned such stakeholder oversight to be a meaningful and ongoing component of biobank governance. Finally, EngageUC deliberants strongly supported the initiation of a campaign of public education about biobanking and biomedical research, which they felt would allow potential donors and the public more broadly to better understand not only individual requests for consent to medical research, but also the role of these efforts in medical discovery and population health.

Our work with EngageUC supports the utility of deliberative democracy-informed community engagement as a strategy to inform biobank oversight (Carman et al. 2015). The methods used have been successful in biobank planning in the U.S. and abroad (Olson et al. 2013, Burgess 2014, McWhirter et al. 2015). Establishing adaptive governance, rather than relying on specific prohibitions or choices from a decades-old consent document, will allow biorepositories to respond to emerging ethical concerns (O'Doherty et al. 2011). For example, with the counsel of stakeholder-based oversight boards, biobank leaders can address the appropriate return of individual research results to participants while at the same time respecting the donor's right "not to know" genetic findings. Such decisions must have the benefit of up-to-date information about genotype/phenotype correlations and awareness

of realistic and actionable options for prevention and treatment. And as requirements for widespread sharing in an era of “Big Data” emerge, procedures for protecting privacy will benefit from the existence of community governance, assuring that donor values are represented at the table when decisions are made. The experience of EngageUC demonstrates the critical link between broad consent and robust governance. As the U.S. implements President Obama’s “Precision Medicine” initiative, any proposal for creating a national biorepository must get this balance right and, to do so, must invest in—and maintain its investment in—such ongoing oversight and governance. Bold new initiatives in this field must be sure to include appropriate resources for the important ethical work of diverse stakeholders in governance and oversight. Broad consent can only be considered an ethical practice when careful attention is given to critical features of downstream biobank governance, including community oversight of data access and ongoing evaluation.

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