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Have We Asked Too Much of Consent?

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Paul Appelbaum and colleagues propose four models of informed consent to research that deploys whole genome sequencing and may generate incidental findings. They base their analysis on empirical data that suggests that research participants want to be offered incidental findings and on a normative consensus that researchers incur a duty to offer them. Their models will contribute to the heated policy debate about return of incidental findings. But in my view, they do not ask the foundational question, In the context of genome sequencing, how much work can consent be asked to do?

I understand the desire to get consent "right." There is magic in consent. When fully realized, it is a communicative act that alters moral relations, authorizing activities that would otherwise be forbidden. My view, though, is that the focus on consent in contemporary biomedical research has become the modern equivalent of a fetish.[1] Recitations of consent's key components in consent forms and institutional review board protocols have a liturgical feel. Name an issue in human research protection, and the answer is "more consent." American research institutions and others around the world schooled in their ways have built a vast institutional structure devoted to enforcing consent. IRBs spend the bulk of their time reviewing and tweaking consent documents. Yet mounting evidence suggests the distance between the ideal of consent and its actual practice.[2]

I first faced these issues during the Clinton administration when I served on the Secretary's Advisory Committee on Genetic Testing. The genome was being mapped, and I recall Francis Collins, then director of the National Human Genome Research Institute, bringing in a table-sized map of the base pairs of one human chromosome. People hovered around it in stunned silence.

Although the data deluge created by the "thousand dollar genome" was far in the future, we debated its implications, wondering if some tests should be allowed into the market only if they were accompanied by requirements for formal informed consent. In what now seems like quaint language, we worried about the implications of "multiplex" genetic testing. Even then, we recognized that the ideal of full disclosure of all risks and benefits of a particular genetic test, ideally by a trained genetic counselor, would collapse once the volume of genomic data increased. If it took an hour to counsel a patient about one condition, what

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would happen if panels of test could simultaneously offer multiple findings? We were beginning to see the limits of consent, even before the advent of whole genome sequencing.

What alternatives might we consider? American bioethics has been dominated by the goal of individual control, but other approaches are emerging. I have been involved in several efforts to rein in consent, without abandoning it, by employing the techniques of deliberative democracy in systems of governance for large genomic research projects. In one case, we assembled a representative citizens group small enough to meet face to face, gave them detailed information about genomic research, and over four days provided an environment suitable for true deliberation, including about trade-offs among competing social goods. One key outcome was the creation of a citizen-led Community Advisory Board that could consider complex topics such as whether unexpected research findings should be offered to research participants.[3] The CAB also deliberated extensively about best practices for respectful engagement with potential research participants, about how to ask permission on recruitment, and how to handle unexpected findings.

In this model, the meaning and moral force of the initial consent derives not from specific upfront choices, but from consent to a governance scheme. What is consented to is a decision-making process. A participant agrees to be governed by the deliberations of others.[4] Discussion of actual findings occurs later, when the findings are identified, much as in the second model offered by Appelbaum et al. Consent to governance overcomes the main criticism of a phased approach: the fear that participants might feel coerced into learning a genetic finding simply because someone telephones saying, “We know something about your health. Do you want to know, too?” The participant knows that careful consideration has gone into the decision to offer a particular finding, and that like-minded people, not simply experts, have carefully debated whether that type of information should be offered.

A caveat may be needed. Some people, though probably not many, may want to opt out of any or all return of incidental findings. The American College of Medical Genetics guidelines for return of incidental findings in clinical whole genome analysis initially recommended limiting patient choice when sequencing was performed, relying instead on the deliberations of an expert panel, but an intense, year-long debate about the guidelines reveals that such proposals will be criticized for violating an individual’s right “not to know.” ACMG now recommends an up-front “opt out” of incidental findings.

Given the aspirational goals of consent—respecting the dignity of research participants, not simply reducing harms—I have agonized about proposals that seem to bypass consent. But I am heartened by the quality of discussion and debate that can occur in deliberative community engagements. By contrast, the ritual of informed consent often masks the very thing it purports to enact.

It has become clear to me that creating governance schemes based on deliberative theory returns the consent concept to its original meaning in political philosophy. The focus turns away from a ceremony of individual control and choice. Instead, consent is about giving up control, agreeing to accept a set of procedures and practices created and executed by a group

of fellow citizens; it is “consent to be governed.” Yet respect for individual sovereignty is not abandoned. Rather, when a patient decides whether to enter a research study, the deliberative focus switches from genes to governance schemes. Personal sovereignty is not violated when research participants who will share in the benefits of genomics knowledge are given the opportunity to consent to be governed.

Such a novel system for engaging with research participants would of course require careful study and evaluation before it was widely adopted. And admittedly, it may be difficult to implement in the current regulatory regime. But I would argue that IRBs have the authority to authorize experiments that test novel methods, even though exercising that authority requires a reexamination of the dominant liturgy.

An approach to the incidental findings dilemma based on community governance has many strengths. Most importantly, the likely volume and inherent uncertainty of incidental results undermine authentic individual consent. Also, since much genomic research is observational, not interventional, participants are less likely to have a therapeutic misconception about it. Governance models are also better able to minimize the population-level harms that may arise in genomic research. A well-designed governance system will assure ongoing community engagement as the meaning and utility of genomic data constantly transform. Relying on governance models also reduces the time and expense of up-front informed consent. Robust community involvement in governance has costs, but its flexibility and adaptability remove the expense of going back to research participants and “reconsenting” them for the return of new categories of incidental findings.

Giving up choice may seem archaic in a medical marketplace of infinite options, in which a new subjectivity based on consumer participation and self-management is developing in tandem with direct-to-consumer genomics. I hope an alternative, favoring talk over technology and community wisdom over individual control, will prevail.

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