Enabling Responsible Public Genomics

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In the few short months since its launch, we’ve found the Genomics Law Report to be a flexible forum for discussing the legal implications of current developments in the fields of genomics and personalized medicine. Often what reaches the pages of the GLR, however, represents only the highlights from more detailed research and analysis that we undertake in order to thoroughly understand these issues and accurately advise our clients.

We have collected some of that more detailed research and analysis in a law review article, “Enabling Responsible Public Genomics,” to be published next spring in the journal Health Matrix: Journal of Law-Medicine. Here’s the abstract for the article:

As scientific understandings of genetics advance, researchers require increasingly rich datasets that combine genomic data from large numbers of individuals with medical and other personal information. Linking individuals’ genetic data and personal information precludes anonymity and produces medically significant information—a result not contemplated by the established legal and ethical conventions governing human genomic research. To pursue the next generation of human genomic research and commerce in a responsible fashion, scientists, lawyers, and regulators must address substantial new issues, including researchers’ duties with respect to clinically significant data, the boundary between genomic research and commerce and the practice of medicine, and the challenges to privacy presented by genomic data.

This Article presents a new model for understanding and addressing these new challenges, at its core a “public genomics” premised on the idea that ethically, legally, and socially responsible genomics research requires openness, not privacy, as its organizing principle. Responsible public genomics combines the data contributed by informed and fully consenting information altruists and the research potential of rich datasets in a genomic commons that is freely and globally available. This Article examines the risks and benefits of this public genomics model in the context of an ambitious genetic research project currently under way—the Personal Genome Project—and (i) demonstrates that large-scale genomic projects are desirable, (ii) evaluates the risks and challenges presented by public genomics research, and (iii) determines that the current legal and regulatory regimes restrict beneficial and responsible scientific inquiry while failing to protect participants. The Article concludes by proposing a modified normative and legal framework that embraces and enables a future of responsible public genomics.

If you’re interested in diving deeper into some of the issues we’ve covered here at the GLR—including the challenges of achieving informed consent in an era of large-scale genomic research and of understanding the messy thicket of law and regulation into which public genomics has emerged—a complete draft of the article (submitted in August and already out of date in some respects) is available through SSRN.

We’ll be updating the article between now and publication, so if you have questions or suggestions please feel free to put them in the comments or to contact us directly.