International Governance Approaches to Whole Genome Sequencing: Who Governs Return of Results & Incidental Findings?

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ABSTRACT:
Debate rages in the U.S. and internationally over whether researchers, their institutions, biobanks, and funders such as NIH have duties to offer back to research participants incidental findings and individual research results of clinical importance that are discovered in the research process. This crucial debate, deemed by NIH Director Francis Collins "one of the thorniest current challenges in clinical research" (*NYT* 8/25/12) raises profound questions about research governance, whether to maintain the traditional separation between research and clinical care in an era of translational science, and what governance mechanisms – at the local institutional level, the biobank and data archive level, the national level of funders and regulators, and internationally -- are needed to answer these questions. At stake is the future conduct of research in genomics and other domains (such as neuroscience) that routinely generate clinically significant information, especially with the advent of whole genome sequencing (WGS). Even more profoundly, at issue is the future architecture of health law and bioethics, which have traditionally dichotomized research and clinical care, creating two very different oversight regimes. The authors are part of an NIH-supported research team investigating different countries' approach to these questions, to lead an invitational International Workshop at the Brocher Centre in Switzerland in Nov. 2013. This paper analyzes emerging regulatory, ethical, and policy approaches in countries at the forefront of this debate, including the U.S., U.K., Canada, Australia, Israel, Japan, and Spain, as well as approaches embraced by the European Union, and international organizations such as HUGO and P3G. This comparative work is essential to the ELSI 2.0 Initiative (*Science* 5/11/12), to create mechanisms for global cooperation and governance of pressing genomics issues. The authors compare (1) substantive recommendations on how to manage return of results and incidental findings, (2) process recommendations on what bodies should manage and govern this process and how, and (3) what governance mechanisms are used to generate those recommendations. This analysis breaks new ground by creating a much broader comparative data set than exists in the literature to date, and a data set that explicitly focuses on questions of governance. The authors investigate the broad range of approaches evident, from non-governmental recommendations that emphasize local decision-making, to the use of national statute in order to require return of results. This comparative work is essential to illuminate governance options, the consequences of selecting among those options, and opportunities for international harmonization in an era of increasingly international genomics research and innovation.

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