

Toward the ethical treatment of whole genome research participants

Recent technological developments have made it possible for scientists to sequence an entire human genome, but these advances may be a mixed blessing. While much has been made of the benefits of whole-genome sequencing, from improved disease diagnosis to rational drug design, the impacts on the privacy and autonomy of individual participants has received much less scrutiny. In a new essay published in the open-access journal *PLoS Biology*, Timothy Caulfield and his colleagues argue that the ability to sequence a person's entire genome has created a whole new set of moral challenges that standard research ethics guidelines were not designed to solve.

Several aspects of whole-genome sequencing challenge existing research ethics norms. Some of the most pressing ethical issues arising from whole genome research include the vast amount of data produced, the uncertainty regarding future research uses of the data, implications of the data for family members, and the technological ability (and expectations) to publicly release the data. To date, very little effort has been put into providing new ethical standards to address these unique challenges.

With an eye toward remedying this oversight, Caulfield et al. offer a consensus statement aimed at providing "ethically rigorous and practical guidance for investigators and research ethics boards." The consensus statement, a product of a workshop involving an interdisciplinary panel of eminent bioethicists, lawyers, and researchers, tackles the central issues facing whole-genome research: informed consent, the right to withdraw from research, the return of results, and the public release of data. In each case, the authors argue, the public dissemination of collected data presents challenges to the standard methods researchers use to protect participants' privacy and autonomy. In whole-genome research, participants quickly lose control over access to their personal information, and they run the risk of "genetic profiling." Protecting participants in whole genome research studies requires updating informed consent to include information about future use, the limited ability to withdraw information, disclosure of research results, and the potentially wide distribution of personal data.

Central to Caulfield et al.'s recommendations is the use of "robust governance and oversight mechanisms." Review boards must play a much larger role in genomic research than it has in other areas, the authors argue, "in part because the unique challenges associated with the research make it impractical to satisfy the norms, tools, and processes usually utilized to respect autonomy." Even if controversial events are rare, responding to these concerns is essential, they maintain, because "history has told us that they do occur and can have a devastating impact on public trust and the research environment."

Fully acknowledging that many related policy issues also warrant attention--including commercialization and patenting, for example--Caulfield et al. urge immediate action on whole genome research ethics guidance, while the ethical, legal, and social implications of this rapidly evolving field continue.

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