

This response was submitted to the consultation held by the Nuffield Council on Bioethics on 'The linking and use of biological and health data' between 17 October 2013 and 10 January 2014. The views expressed are solely those of the respondent(s) and not those of the Council.



PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

January 10, 2014

Mr. Tom Finnegan
Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

Dear Mr. Finnegan,

1. I am writing on behalf of Dr. Amy Gutmann, Chair, and the U.S. Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) to respond to the Nuffield Council on Bioethics open consultation on views and evidence regarding the linking and use of biological and health information.
2. Two of the Bioethics Commission's past reports, *Privacy and Progress in Whole Genome Sequencing*, released in October 2012 (available at <http://bioethics.gov/node/764>), and *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*, released in December 2013 (available at <http://bioethics.gov/node/3183>), are particularly relevant to your open consultation.

What are the new privacy issues?

3. As the Bioethics Commission discussed in *Privacy and Progress*, whole genome sequencing has progressed from being one of our nation's boldest scientific aspirations to becoming a readily available technique for determining an individual's genetic blueprint. As the cost to sequence an entire human genome continues to fall, the potential exists for rapid advances in wellness and health care resulting from this new technology. Essential to achieving those advances is sharing, comparing, and pooling data and information. However, as the ease with which the acquisition and sharing of whole genome sequencing data and information increases, so do questions and concerns about privacy and security.
4. In *Privacy and Progress*, the Bioethics Commission recommended strong baseline protections for whole genome sequence data to protect individual privacy while also leaving ample room for data- and information-sharing opportunities that propel scientific and medical progress. The Bioethics Commission urged the U.S. federal and state governments to

ensure a consistent floor of individual privacy protections covering whole genome sequence data regardless of how the data were obtained. It also recommended that policies and infrastructure protect safe sharing of data through ethical accountability from all those who handle whole genome sequence data.

5. The Bioethics Commission also supports ongoing exploration and development of best practices that separate possession of, access to, and use of data recognizing that the *use* of data (including misuse and unauthorized use) will, in some cases, be of greater ethical salience than either access to or possession of such data. In all cases researchers, clinicians, and others with authorized access to whole genome sequence data should be guided by professional ethical standards so that they do not intentionally or inadvertently misuse these data.

What are the opportunities for, and the impact of, the use of linked biomedical data in research? What are the opportunities for, and the impacts of, data linking in medical practice?

6. In *Privacy and Progress* the Bioethics Commission also recognized that realizing the promise of whole genome sequencing requires widespread public participation and individual willingness to share genomic data and relevant medical information. The use of biomedical data linked to rich medical histories allows researchers to make more nuanced and accurate connections between disease states and genetic variation. This type of in-depth research requires public trust that any whole genome sequence data shared by individuals with researchers and clinicians will be adequately protected. *Privacy and Progress* outlines several concrete recommendations for bolstering the privacy protections of such data, including holding all persons who work with genetic sequencing data accountable to professional ethical standards, stripping databases of traditional identifiers whenever possible (including when data are at rest), and ensuring that third-party entrustment storage and analysis complies with data privacy and security requirements.
7. In *Anticipate and Communicate*, the Bioethics Commission looked at one specific potential impact of the use of biomedical data in research and medical practice: that of incidental and secondary findings—defined respectively as findings arising outside the original purpose for which a test or procedure was conducted, and findings that are actively sought but that are not the primary purpose for which the test or procedure was conducted. Such findings can be lifesaving, but also can lead to uncertainty and distress if they are unexpected or identify conditions for which no effective treatment is available. As technology advances, the likelihood of discovering incidental and secondary findings is expected to increase.
8. While the Bioethics Commission found that researchers generally have no ethical duty to actively look for secondary findings, it did recommend that all practitioners, including researchers and clinicians, anticipate and communicate clearly the plan for incidental and secondary findings to the best of their ability before testing occurs. These management plans provide the recipient as much information as possible to guide informed decision making. To aid in this process, professional organizations and experts should continue to enumerate all anticipatable findings for various tests and procedures and provide guidance about their

ethical management in context.

We appreciate the opportunity to submit comment on this timely and important topic and hope that the Bioethics Commission's work can help contribute to your own.

Best regards,

A handwritten signature in black ink, appearing to read "Kayte SB". The letters are cursive and somewhat stylized.

Kayte Spector-Bagdady, J.D., M. Bioethics
Associate Director

cc: Amy Gutmann, Ph.D.
Chair