



June 24, 2016

The Honorable Elizabeth Warren
U. S. Senate
317 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Enzi
U. S. Senate
379A Russell Senate Office Building
Washington, DC 20510

Dear Senator Warren and Senator Enzi,

The American Society of Human Genetics (ASHG) thanks you for introducing the Genetic Research Privacy Protection Act (S.2744), and strongly supports passage of the legislation by Congress. At a time when the United States is recruiting over 1,000,000 research participants into the Precision Medicine Initiative (PMI), it is imperative that Congress passes a measure to guard against the inappropriate use of the Freedom of Information Act (FOIA) to gain access to research participants' genetic information. Similarly, it is essential that Congress builds on existing privacy protections for participants by strengthening certificates of confidentiality.

ASHG, founded in 1948, is the world's largest genetics professional society, with nearly 8,000 members representing all areas of research and application in human genetics. The Society's membership comprises diverse professionals in genetics, molecular biology, medicine, biochemistry, and other areas of experimental science, as well as computational science, statistics, and epidemiology. The Society recognizes the invaluable contribution of the public in volunteering to participate in biomedical research, and believes that it is important to minimize any potential harm that could come to research participants as a result of their participation. Establishing strong measures to protect participants' privacy is an essential component of this protection.

Each person's genome is unique and contains sensitive information that, for instance, provides indicators of health risks for the individual and relatives. Our genomes differ sufficiently that scientists have shown that it is possible to identify an individual from his or her genome sequence and other publicly available information. The Society therefore supports the policy that the National Institutes of Health (NIH) has established to keep private the genomic information of research participants (<https://gds.nih.gov/03policy2.html>), where individual-level research data housed by the NIH is made available only for research purposes.

However, since this research information is housed in federal databases, it constitutes a collection of government records, and the policy is therefore vulnerable to FOIA requests for access to individuals' information. Indeed, the September 2015 PMI Working Group Report (<http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf>) reported that the NIH has received FOIA requests for genomic data. Although NIH has denied these requests on the basis of existing exemptions in FOIA, the report notes that such denials may not be successfully defended if challenged in court. This is why ASHG supports the provisions of S.2744 that establish a statutory exemption for genomic and other individual-level research data, consistent with recommendation 7.8 of the report.



Current privacy protections for genetic information in the possession of biomedical researchers are also insufficient. As established in Section 301(d) of the Public Health Service Act, researchers may request certificates of confidentiality to protect the privacy of participants in health-related research, withholding from individuals not connected with the research the names of participants or information that could be used to identify them. However, such protections are limited because there is no requirement to acquire certificates or to use them. Acknowledging this problem, the PMI Working Group Report recommended that investigators using identifiable information be required to acquire certificates, and that the investigators be prohibited from voluntarily disclosing the information.

Congress has already responded to this issue. The Consolidated Appropriations Act of 2016 established that, '...in order to strengthen privacy protections for human research participants, NIH shall require investigators receiving NIH funding for new and competing research projects designed to generate and analyze large volumes of data derived from human research participants to obtain a certificate of confidentiality'. However, this law is only in effect for Fiscal Year 2016. Also, while it requires some researchers to acquire certificates, it does not require them to use the protections afforded by the certificates to deny data requests unrelated to research.

ASHG therefore supports the provisions of S.2744 that permanently strengthen the protections afforded by certificates of confidentiality. S.2744 requires that investigators are in possession of certificates if they conduct research that includes the collection of individuals' sensitive information. The bill further mandates the use of such certificates in response to requests for data for non-research purposes. Importantly, the bill would enable certificates to be issued to investigators automatically, thereby reducing the administrative burden for investigators and their research institutions.

The Society thanks you for your leadership in strengthening protections for research participants. The protections established by S.2744 against the inappropriate use of research data will reassure research participants that their genomic and other research data will remain out of public hands, thereby encouraging research participation and maintaining public trust in the federal research enterprise. Please ask your staff to reach out to Derek Scholes (dscholes@ashg.org; (301) 634-7330) on ASHG's staff if there is any way in which the Society can be of assistance.

Sincerely,

Harry C. Dietz, MD
President