Update to “Data Security and President Obama’s Precision Medicine Initiative”

In the Spring 2015 issue, we published a news brief on President Obama’s announcement of the Precision Medicine Initiative at his State of the Union address. The Initiative includes the creation of a $215 million national biobank with the hope of personalizing individual treatment through genomic data (White House 2015a). However, many privacy concerns developed following the release of this plan to personalize medicine (Klugman 2015). On November 13, 2015, the White House released a set of privacy and trust principles to provide a legal framework intended to minimize potential breaches in patient privacy.

These principles were formed as an inter-agency effort with the White House Office of Science and Technology Policy, the Department of Health and Human Services Office for Civil Rights, and the National Institutes of Health. The principles’ formation included consultation with experts, bioethics literature, public opinion, and the policies of already existing biobanks.

From this foundation, the group developed the following categories for privacy principles (White House 2015b):

1. Governance: Ensure participants have active roles in the Initiative, through collaboration with researchers or by having their needs represented and considered in decision-making
2. Transparency: Provide information to participants through all stages of the Initiative, and also make the information easily accessible and comprehensible to a diverse group of individuals.
3. Participant empowerment: Help individuals understand their own health data in order to make informed decisions
4. Respect for participant preferences: Dynamic and ongoing consent, in which individuals can change their decisions to participate at any moment
5. Data sharing, access, and use: Define data on different tiers, which vary in how open and accessible certain information can be, and explicitly ban selling any health data for advertisement purposes
6. Data quality and integrity: Commit to providing the most accurate information at all times.

In addition to providing a legal and ethical framework for precision medicine, the interagency group also plans on developing administrative, technical, and physical safeguards for protecting genomic data (White House 2015b).

References

Update to “Direct-to-Consumer Genetic Testing: An Examination of Privacy and Security Concerns”

In the Fall 2014 issue, we published an article on the ethical implications of direct-to-consumer genetic testing, focusing on the company 23andMe. In November 2013, the Food and Drug Administration banned 23andMe from continuing to sell its direct-to-consumer genetic testing product. The ethical concerns were that individuals could misinterpret direct-to-consumer results, the unregulated industry was engaging in false advertising, consumers’ data protection and privacy were weak, and the company was using consumers’ data for medical research without undergoing the IRB-approval normally required of research using sensitive personal data (Pollack 2013).

After two years, 23andMe is now back on the market providing lower-risk genetic tests. Instead of offering genetic testing for the individual consumer to weigh his or her risk of developing various diseases, the company is providing genetic testing on carrier status (Pollack 2015a; Pollack 2015b). The company decided to wait until now to release its carrier tests, which assess whether the consumer carries the recessive allele for 36 different diseases, including cystic fibrosis, sickle cell anemia, and Tay-Sachs. In addition to being back on the market, 23andMe has announced its intention to start developing medical drugs. Richard Scheller, former Vice President of Research and Early Development at Genentech has joined 23andMe to head this initiative (Pollack 2015b).

References