What about Privacy and Progress in Whole Genome Sequencing?

Conclusions

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PRIVACY and PROGRESS in Whole Genome Sequencing

Presidential Commission for the Study of Bioethical Issues

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“As our nation invests in science and innovation and pursues advances in biomedical research and health care, it’s imperative that we do so in a responsible manner.”

- President Barack Obama

Executive Order 13521 of November 24, 2009

Establishing the Presidential Commission for the Study of Bioethics Issues

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment. There is established within the Department of Health and Human Services the Presidential Commission for the Study of Bioethical Issues (Commission).

Sec. 2. Mission.

(a) The Commission shall advise the President on bioethical issues that may emerge as a consequence of advances in biomedicine and related areas of science and technology. The Commission shall pursue its work with the goal of identifying and promoting policies and practices that ensure scientific research, healthcare delivery, and technological innovation are conducted in an ethically responsible manner. To achieve this goal, the Commission shall:

(i) identify and examine specific bioethical, legal, and social issues related to the potential impacts of advances in biomedical and behavioral research, healthcare delivery, or other areas of science and technology;

(ii) recommend any legal, regulatory, or policy actions it deems appropriate to address those issues; and

(iii) critically examine diverse perspectives and explore possibilities for useful international collaboration on these issues.

(b) In support of its mission, the Commission may examine issues linked to specific technologies, including but not limited to the creation of stem cells by novel means; intellectual property issues involving genetic sequencing, biomarkers, and other screening tests used for risk assessment; and the application of neuro- and robotic sciences. It may also examine broader issues not linked to specific technologies, including but not limited to the protection of human research participants; scientific integrity and conflicts of interest in research; and the intersection of science and human rights.

(c) The Commission shall not be responsible for the review and approval of specific projects.

(d) The Commission may accept suggestions of issues for consideration from executive departments and agencies and the public as it deems appropriate to support its mission.

(e) In establishing priorities for its activities, the Commission shall consider, among other things, the significance of particular issues; the need for legal, regulatory, and policy guidance with respect to such issues; the connection of the issues to the goal of Federal advancement of science and technology; and the availability of other appropriate entities or fora for deliberation on the issues.

(f) The Commission is authorized to conduct original empirical and conceptual research, commission papers and studies, hold hearings, and establish committees and subcommittees, as necessary. The Commission is authorized to develop reports or other materials.

Sec. 3. Membership.

(a) The Commission shall be an expert panel composed of not more than 13 members appointed by the President, drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences, at least one and not more than three of whom may be bioethicists or scientists drawn from the executive branch, as designated by the President.

(b) The President shall designate a Chair and Vice Chair from among the members of the Commission. The Chair shall convene and preside at meetings of the Commission, determine its agenda, and direct its work. The Vice Chair shall perform the duties of the Chair in the absence or disability of the Chair and shall perform such other functions as the Chair may from time to time assign.

(c) Members shall serve for a term of 2 years and shall be eligible for reappointment. Members may continue to serve after the expiration of their terms until the appointment of a successor.

Sec. 4. Administration.

(a) The Department of Health and Human Services shall provide funding and administrative support for the Commission to the extent permitted by law and within existing appropriations.

(b) All executive departments and agencies and all entities within the Executive Office of the President shall provide information and assistance to the Commission as the Chair may request for purposes of carrying out the Commission’s functions, to the extent permitted by law.

(c) The Commission shall have a staff headed by an Executive Director, who shall be appointed by the Secretary of Health and Human Services in consultation with the Chair and Vice Chair.

(d) Members of the Commission shall serve without compensation, but shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701–5707), consistent with the availability of funds.

Sec. 5. Termination. The Commission shall terminate 2 years after the date of this order unless extended by the President.

Sec. 6. General Provisions.

(a) This order supersedes Executive Order 13237 of November 28, 2001.

(b) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.), may apply to the Commission, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines that have been issued by the Administrator of General Services.

(c) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(d) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(e) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.
The Bioethics Commission’s goal was to find most feasible ways of reconciling

- Enormous medical potential of whole genome sequencing, with

- Pressing privacy and data access issues raised by low-cost whole genome sequencing
Current U.S. governance and oversight of genetic and genomic data do not fully protect individuals from the risks associated with sharing their whole genome sequence data.

Future policies must reconcile anticipated societal benefits with the potential privacy risks to individuals.

Realizing the promise of whole genome sequence requires widespread public participation and individual willingness to share genomic data and relevant medical information.
Five areas for ethical analysis

- Strong baseline protections while promoting the data access and sharing required for progress
- Data security and access to databases
- Informed consent
- Facilitating progress in whole genome sequencing
- Public benefit
• Whole genome sequencing privacy breach concerns are no longer hypothetical

• Study successfully uncovered full identities of 50 individuals
• Stranger Visions: New York artist Heather Dewey-Hagborg uses found DNA to recreate 3-D human faces

• Artist looks in public places for objects like strands of hair, cigarette butts, chewed pieces of gum
Reconciling Privacy and Progress

• Requires reconsideration of distinction between ‘identifiable’ and ‘non-identifiable’
  – Less like a bright line
  – More like a continuum

• Less about what makes something *identifiable* and more about what keeps it *private*
• Privacy is secured or breached based on several steps
  – Individual’s decision to disclose information
  – Others’ access to the data
  – Others’ use/misuse of data

• Ethical tools to protect privacy
  – Informed consent
  – Consistent floor of protections for data access
    • Security of data
    • Professional expectations
    • Accountability and consequences for violators
Informed consent must
- Inform about the potential risks (including those related to informational privacy)
- Describe benefits of participation
- Ascertain participant preferences for data use
• Laws, regulations, institutional policies, and IT systems controlling access to data must be explicit, transparent, and consistent with consent and participant preference.

• Researchers and clinicians, along with all persons who work with genomic data, must be
  – Guided by professional ethical standards related to privacy and confidentiality
  – Held accountable to all state and federal laws and regulations in case of breaches of identity or confidentiality.
• Addressing incidental findings related to whole genome sequencing

• Ethical analysis and recommendations addressing incidental findings
  – In 3 contexts
    • Clinical care, research, direct-to-consumer testing
  – Resulting from 3 modalities
    • Large scale genetic sequencing, imaging, biological specimens

• Report to President by end of 2013
Thank you

Discussion