



May 24, 2012

Amy Gutmann, PhD, Chair
Presidential Commission for the Study of Bioethical Issues
1425 New York Avenue, NW
Suite C-100
Washington, DC 20005

Dear Dr. Gutmann:

The American College of Physicians (ACP) submits this letter in response to the privacy and access in relation to the integration of large-scale human genome sequencing into specialty society and second-

that there should be tighter controls against improper re-identification of de-identified patient or subject data.³

In light of the very significant impact that inappropriate genetic data may have, ACP believes that researchers should be required to obtain fully informed and transparent consent from the subjects of genetic research.¹ Fully informed and transparent consent requires the disclosure of all potential uses of patient biological materials and data. The consent process should be in language understandable to research subjects and needs to include the preference of the research subject regarding future contact for notification about results and/or consent for additional research participation. Research should be limited to the use specified by the protocol during the informed consent process. Research subjects should be made aware that it may not be possible to withdraw their biological materials from research use once they are de-identified. Full disclosure of the risks and benefits of research involving biological material allows research subjects to make well-informed decisions.¹

Consent is also an issue of concern with respect to the use of existing genetic materials.

A handwritten signature in black ink, appearing to read "David Brown". The signature is written in a cursive, flowing style.

Snyder L. American College of Physicians Ethics, Professionalism, and Human Rights Committee. Ethics Manual, sixth edition. *Ann Intern Med.* 2012; 156:73-104.

² Rothstein MA. Is deidentification sufficient to protect health privacy in research? *Am J. Bioeth.* 2010; 10:3-11.

³ American College of Physicians. Health Information, Technology and Privacy: A Position Paper. July 2011

⁴ Human subjects research protections: enhancing protections for research subjects and reducing burden, delay and ambiguity for investigators. 76 *Federal Register* 143 (July 26, 2011) pp. 44512-44531.

⁵ Institute of Medicine. Beyond the HIPAA privacy rule: enhancing privacy, improving health through research. Washington, DC: National Academies Press; 2009.