

Citizens for Responsible Care and Research, Inc. (CIRCARE)
(A wholly independent, volunteer, nonprofit, tax-exempt organization,
incorporated under the laws of the State of New York)

1024 North 5th Street
Philadelphia, Pennsylvania 19123-1404
215.627.5335
<http://www.circare.org>; web@circare.org

May 11, 2012

Public Commentary
Presidential Commission for the Study of Bioethical Issues
1425 New York Avenue NW, Suite C-100
Washington, DC 20005

VIA info@bioethics.gov

In re: U.S. Department of Health and Human Services, Office of the Secretary,
Presidential Commission for the Study of Bioethical Issues, Request for
Comments on Issues of Privacy and Access With Regard to Human Genome
Sequence Data, 77 Fed. Reg. 18,247 (2012).

This inquiry comes at a time of:

- Aggressive research, commercial, and government (ranging from research sponsorship to law enforcement) interest in, acquisition of, and exploitation of identifiable genetic information and biosamples; and
- Renewed concern for personal privacy and possible, dystopian consequences of its violation—especially in the cross-linking of personal data. The Supreme Court of the United States has found unanimously that warrantless, sustained Global Positioning System monitoring of a suspect's vehicle violates the Fourth Amendment to the Constitution, and justices have urged Congress to enhance reasonable expectations of privacy; the European Union is bolstering its already strong privacy protections; and the Department of Health and Human Services has encountered privacy-based objections to loosening of human subjects research protections.

We urge the Commission and cognizant government agencies to employ the precautionary principle in these matters and opt to tighten rather than loosen regulatory policy where personal information and genetic information are involved. There are ways to do this while facilitating meritorious biomedical research, including data exchange, and facilitating appropriate medical uses of genetic information in diagnostics and therapeutics.

Issues of personal privacy, confidentiality, and data security in relation to identifiable human genome sequence data cannot be treated responsibly in isolation from recognition of concurrent related developments and legal gaps in commerce, information technology, government (including law enforcement), and behavioral, social, and biomedical research. Even as anonymization of genetic samples is becoming all but impossible, the furnishing and collection of biosamples are becoming pervasive, as has dependence on the Internet as a condition of participation in society, and data mining has expanded dramatically. The interest of behavioral and social science and law enforcement in exploiting these data sources without individual consent has grown concomitantly—as has the seriousness of consequences of cross-linkages and of unwanted disclosure, particularly where the data and cross-links are posited or assumed as predictive for medical or social pathology.

Personal data are acquired, bought, sold, otherwise transferred, and used often without the actual knowledge of the subject(s) of those data. Data security and sanctions for violation are inadequate, personal remedy for violation is elusive, and Institutional Review Boards, Privacy Boards, and their training materials are oblivious to the ethical and legal implications of existing tort law on invasion of privacy and wrongful use of personal information. If these factors are not taken into account, then ostensibly protective measures distinctive to genomics research and related medical research and health care practice are illusory. Accordingly:

- Informed consent—knowing, revocable, voluntary, in circumstances conducive to voluntariness— should be recognized as an unwaivable ethical and legal precondition to procurement of, access to, and each use of personal genetic information in biomedical, behavioral, and social research. Blanket consents and open-ended research consents violate human subjects protection law and should not be allowed.
- Consent documents for all genetic research and tissue donation should include prominent warnings that confidentiality cannot be guaranteed, that security is not absolute, and that cross-linkage could result in disclosure or inference of information damaging to the research subject.
- Except when in use, all data sets containing personal genetic information or behavioral and social research information used in cross-linkage and longitudinal genetic research should be highly encrypted and subject to stringent access controls.
- Behavioral and social research involving genetic data, whether or not ostensibly unidentifiable, should be:
 - Deemed high risk with no direct benefit to the subject;
 - Prohibited without individual, informed consent for each research use; and

- Disallowed for cognitively impaired persons; for prisoners, for civilian and military detainees, for accused persons, parolees, and probationers; for children in child-protection or juvenile justice programs; for other persons who might be subject to undue influence; and for any persons under a legal disability.
- Consents to participation in the National Children's Study should lapse within one year unless renewed, for no more than one year at a time, with prominent warning of possibly serious consequences of data disclosure and cross-linking. As children who were or are subjects of the National Children's Study reach age 18 and annually thereafter if applicable should have the opportunity to revoke all consents to their participation and to have their research records sealed and rendered unidentifiable to the extent possible.
- Highly secure means, at least as strong as credit-card disguised identity systems for Internet payment, should be used in the exchange of personal data within science and for communication with research subjects and tissue donors and persons who have consented to the use of their genetic information for research.
- Unless revoked earlier, consent to research of the kinds discussed here should not be valid for more than one year but may be renewed.
- Subjects of the kinds of research discussed here should have the absolute right to challenge and have corrected or removed any information pertaining to them in cross-linkage studies.
- For research of the kinds discussed here the Certificate of Confidentiality procedure should not be deemed protective.
- Informed consent should be required for cross-linkage and longitudinal involving records review and genetic data, whether or not involving personal contact with subjects.
- Consent to donate tissues for research or to release genetic data for research should not be required in connection with access to or use of healthcare services.
- Cross-linkage and longitudinal studies involving long-stored biosamples procured without individual informed consent should be discontinued unless and until individual informed consent is obtained.
- Study by disinterested legal experts—without client conflicts and not from research institutions, government, or research interest groups—is needed urgently to propose preventive measures, sanctions, and remedies in order to safeguard the confidentiality of research data of the kinds considered here and in order to make whole those individuals whose

privacy and confidentiality have been breached in this connection whether or not intentionally.

Privacy and confidentiality remain a major public concern, as reflected in Pew Research polling, a major Supreme Court ruling, Federal Trade Commission action, and legislative and White House statements. It is a mistake to believe that privacy no longer matters in America and that most individuals now widely surrender their privacy willingly. No small measure of yielding privacy can be attributed to mistaken assumptions of confidentiality and to contracts of adhesion that are the price of engaging in commerce, both on and off the Internet.

Our worry is not about progress in scientifically informed health care but rather about possible misuse of genetic information. Current U.S. legal protections for personal privacy, confidentiality, and security of genetic information are insufficient. These concerns are hardly new and are increasingly valid:

...What is collected, for what purposes, with whom information is shared, and what opportunities individuals have to see and contest records are all matters of policy choice, not technological determinism. Man cannot escape his social or moral responsibilities by murmuring feebly that “the Machine made me do it.”

* * * * *

...Our task is to see that appropriate safeguards for the individual’s rights to privacy, confidentiality, and due process are embedded in every major record system in the nation, particularly the computerizing systems that promise to be the setting for most important organizational uses of information affecting individuals in the coming decades.

National Academy of Sciences, *Databanks in a Free Society* (1972) at 405.

... [A]s recent and rapid advances in biological and medical research made it possible to analyze DNA from almost any minuscule sample of human tissue, concerns about privacy and informed consent have been raised. Complicating these issues is the paucity of information addressing tissue acquisition, use, and storage.

Elisa Eiseman & Susanne B. Haga, *Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples* (RAND, 1999) at 1.

There is no reason to expect that behavioral genetic information will be afforded greater privacy protection than other forms of medical or genetic information. Some constitutional, statutory, or common law theories may be applied to limit some overly intrusive inquiries or unnecessarily extensive disclosures. In general, however, a wide range of substantive limitations in each specific area will need to be enacted to

safeguard the privacy of this information.

How will the law respond?

The law does not operate independently of culture, it follows culture. In the 1920s, when eugenics dominated American scientific thinking, it also dominated American culture and American law. How will the law respond to new discoveries in genetics, including behavioral genetics? To what level of legal scrutiny will claims of behavioral genetics be subjected? How will proven associations of genetics and behavior affect a range of legal doctrines related to privacy, autonomy, nondiscrimination, and societal opportunities? How will unproven or outright bogus assertions be received by the courts?

Legislative and judicial responses to new genetic discoveries will have a major effect on whether we are about to enter an unprecedented period of behavioral genetic determinism and, with it, social disruption, or the promised enlightened era of genetic marvels. While history does not preordain the future, it certainly reminds us of the stakes involved.

Mark A. Rothstein, *The Impact of Behavioral Genetics on the Law and the Courts*, 48 *Judicature* 116 at 123 (1999-2000).

We remind the Commission of statutory intent underlying human subjects research protections: “*to review biomedical and behavioral research involving human subjects . . . in order to protect the rights of the human subjects of such research.*” 42 U.S.C. 289(a).

We remind the Commission also that researchers must earn their trust. Their interests are not superior to those of other persons. Conscientious researchers know that respect for persons is essential for human subjects research and that foregoing or weakening human subjects protections in the name of convenience is to invite distrust and cynicism among researchers and potential and actual research subjects. That would be enormously harmful to conscionable and necessary research.

Citizens for Responsible Care and Research, Inc. (CIRCARE) is the oldest human research protection organization in the United States and is entirely independent. We advocate conscionable research and are dedicated to responsible medicine and effective protection of human subjects in behavioral and biomedical research. We will be pleased to be of further assistance.

Sincerely,

For Citizens for Responsible Care and Research:

Gerald S. Schatz, J.D.

(Of the Bars of the District of Columbia and Pennsylvania)

Vice President, CIRCARE

Reply to:

Elizabeth Woeckner, M.A.
President, CIRCARE
1024 N. 5th S. Philadelphia, PA 19123-1404
E-mail: lizwoeckner@mac.com
Telephone: 267.671.8212

Or:

Gerald S. Schatz, J.D.
Vice President, CIRCARE
10788 Brewer House Rd.
Rockville, MD 20852
E-mail: geraldschatz@att.net
Telephone: 301.984.6142