Citizens' Council on Health Care
CCHC POLICY BRIEF
March 2005

Questions to Ask - Mayo/U. of M. Genetic Research Plan

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People may not understand…that tissue samples they provide may be used for genetic research…They may believe that samples will be discarded after testing, although the law often requires that samples be retained. When samples are obtained as part of medical care, patients may not be told about the possibility that these samples will be stored and used for research…[O]ne investigator has found that documents used to obtain informed consent in genetic research usually do not inform subjects that the samples they provide may be retained and used for research well into the future, including research on disorders unrelated to those for which the subjects originally provided their samples and by investigators at other institutions.

Ellen Wright Clayton, MD, JD, et. al. "Informed Consent for Genetic Research on Stored Tissue Samples." JAMA. 12/13/1995.

RE: Statutory Compliance

Q: Why does there seem to be a MN organization involved in processes designed to circumvent state privacy laws?

The New England Journal of Medicine (NEJM, 11/97) published an article by Dr. L. Joseph Melton III, MD, Mayo Clinic epidemiologist, who expressed concern about the 1996 Minnesota law requiring consent for medical research. He also discussed the 30 year old Rochester Epidemiology Project that, "links Mayo Clinic medical records for the residents of Rochester and of Olmsted County, Minnesota, with those of the other major providers of health care to community residents, thus ensuring nearly complete coverage of the local population."[1] Mayo could do this access and linkage project because of Minnesota law, he claimed.

My letter to the *NEJM* (published 4/9/98) refuted his assertion, pointing out a 1976 state law that assures patients of the right to "approve or refuse" the release of their medical records. In his response, Dr. Melton claimed Project data "were obtained under custodial agreements with the other providers..." In October 1998, Citizens' Council on Health Care (then Citizens for Choice in Health Care) sent Mayo a letter seeking information about these custodial agreements to ascertain Mayo's compliance with state medical records laws. Mayo did not respond. In August 1999, a certified follow-up letter was sent to Dr. Hugh Smith, MD, Chair of the Mayo Board of Governors. There was no response.

RE: Patient consent

Q: Why are many Minnesota patients included in research although they never gave their consent, and do not know?

State Level
Minnesota Statutes (M.S.) 144.335 subd 3a(d) gives *internal* researchers access to medical records without patient consent. Only *external* researchers are required to obtain consent. However, if two letters requesting consent are sent to the last known address of the patient and the patient does not respond, state law allows that patient's consent to be "established." An October 2002 *Minnesota Physician* article written by Dr. Melton indicates 18 percent of Mayo patients giving "passive authorization."

Using the 5.1 million Mayo patients cited by Melton in *NEJM*, at least 918,000 patients have "passively consented" whether they wanted to or not. CCHC's 1998/1999 attempts to obtain a copy of Mayo's notification documents were unsuccessful.

Federal Level
Various federal rules (Common Rule, federal privacy rule, FDA rules) explicitly allow research without patient consent, or allow consent to be waived by Institutional Review Boards (IRB). Inspections of IRBs by the U.S. Office for Human Research Protections reveal *problems*: research conducted without review, failure to obtain effective informed consent, inadequate informed consent, possibility of coercion, and conflicts of interest.[2]

Q: Are patients obligated to participate in medical and genetic research to receive care?

According to Mayo Clinic, yes. In a letter to HHS dated February 15, 2000, Mayo's public comments on the proposed federal medical privacy rule include the following two statements:

"An approach that demands individual authorization for use of records in research creates a ***major impediment*** to this research, which is vital both from the standpoint of society, and the individual patients making decisions about care." *(my emphasis)*

"The Secretary's proposal makes two exceptions to the general rule relating to treatment, payment, and health care operations. The exceptions require individual authorization for any use or disclosure of psychotherapy notes and 'research information unrelated to treatment.' For the same reasons stated above we suggest that ***these exceptions be eliminated***. We believe that all patient information is relevant for purposes of high quality patient care, whether it pertains to mental health, ***genetics***, or any other particular area. Our unit medical record includes all infor-

mation, and is not segmented by a particular area." *(my emphasis)*

John Curd, MD, vice president of clinical development at **Genentech, Inc**. (a genetics corporation which conducts many of its clinical trials at Mayo, according to *The Pink Sheet*, May 1999) told the U.S. Senate: "Now that the Mayo Clinic has spread to at least three states (Florida, Arizona, and Minnesota), and is a pioneer in the development of a computerized medical record, we can look forward to even more productive information stemming from their experience, assuming that ill-advised legislation from states or the federal government relating to patient confidentiality does not dramatically erode our ability to use this information to further medical research."(written testimony, 4/27/99)

However, the **Institute of Medicine** advocates "revitalization" of informed consent, saying it "should be an ongoing process that focuses not on a written form or a static disclosure event, but rather on a series of dynamic and appropriately targeted conversations between the participant and the research staff...[T]he process should ensure that participants clearly understand the nature of the proposed research and its potential risks and benefits to them and society."[3]

RE: Government Access to Patient Data

Q: Will state government be able to do research on citizens using genetic profiles and other medical record data?

The MN Dept. of Health is exempt from patient consent requirements for medical research (Minnesota Statutes 144.335 sub.3b). MDH has full access to medical records, including genetic data, without patient consent. Despite MDH's 2003 withdrawl of a controversial data collection *rule*, the *law* remains (M.S. 62J.301– 62J.43). At least 137 million medical records have already been collected.

The Federal Medical Privacy Rule (HIPAA) provides access without consent for public health and for medical research through §164.512 ("Uses and disclosures for which an authorization or opportunity to agree or object is not required"), and §164.514 (e)(2)(i) - an *identifiable* "limited data set" may be disclosed "for the purposes of research, public health, or health care operations." The HHS specifically notes, "the limited data set is *not deidentified* information..."[4] *(my emphasis)*

RE: Ethics and Electronics

Q: How informed is the legislature about research at Mayo and the U, and how comfortable would the public be?

Research Initiatives: According to *National Geographic Magazine* (1/25/05): "In Minnesota last year researchers at the Mayo Clinic created pigs with human blood flowing through their bodies." The Mayo Clinic testified that they are attaching genetic markers to body tissues in a prostate cancer study; and that DNA sequencing equipment will be bought. *What other research is planned using the tissues, serum, DNA and body parts of the public? Stem cell research, human cloning, nanotechnology?*

Electronic Databases:
Dr. Frank B. Cerra, M.D., senior vice president for health services at the University of Minnesota writes, "Mayo Clinic has invested $150 million to develop an unique digital database of more than 4 million patient records and 10 million tissue and serum samples." (*Minnesota Medicine*, 2003).

The *St. Paul Pioneer Press* notes, "Mayo Clinic asked IBM…to help it build an electronic warehouse of medical records including the patient's genetic profile..." ("Genetic Gold Mine," Aug. 24, 2003).

RE: Genetic Research

Q: What is the impact of unconsented genetic research?

Implications include potential discrimination in insurance coverage and employment, lawsuits against health care institutions, violation of religious or cultural beliefs, the fluidity of state and federal laws; psychological and financial impact of predictive testing; distrust of medical institutions; statutory restrictions on lifestyle, marriage, or procreative choices. One example:

"[I]n genetic studies conducted at the National Institutes of Health, nearly 32 percent of eligible people offered a test for breast cancer risk declined to take it. The overwhelming majority of those who refuse cite concerns about health insurance discrimination and loss of privacy as the reason."[6]

Q: What obligations does the State of Minnesota have to citizens with regard to taxpayer-funded genetic research?

"The protection of research subjects is an end in itself. If that means you can't do research, so be it," says noted health privacy expert, George Annas, J.D., M.P.H.[6]

A 2000 Gallup Poll Survey on medical privacy found: **93%** say researchers should not be allowed to study an individual's genetic information without consent, and **67%** oppose researchers seeing medical records without the patient's permission.[7]

Q: What Minnesota law protects citizens against the unconsented use of human tissues and human body parts for medical or genetic research?

None!

ENDNOTES

[1] Melton LJ III. "The threat to medical-records research." N Engl J Med 1997; 337: 1466-70.
[2] "OHRP Compliance Activities: Common Findings and Guidance." Office for Human Research Protections. 7/10/2002.
[3] "Responsible Research: A Systems Approach to Protecting Research Participants." Institute of Medicine. October 2002.
[4] "Standards for Privacy of Individually Identifiable Health Information; Final Rule." Federal Register. August 14, 2002, p. 53236.
[5] OCR HIPAA Privacy, December 3, 2002.
[6] George J. Annas, J.D., MPH, Boston University School of Public Health. National Ethics Conference, Baltimore, MD. November 15, 1998. (quote taken out of author's notes from attendance at event).
[7] "Public Attitudes Toward Medical Privacy." The Gallup Organization (for the Institute for Health Freedom), September 2000.