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

Twila Brase, R.N., President

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.


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.” 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.

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-