



What Consent? - MN's Medical & Genetic Research Law

(Minnesota Statutes (M.S.) 144 and 62J)

Minnesota state law *denies* most consent rights for patients regarding use of their individually-identifiable medical records for medical research. The law is silent on use of human tissues for medical and genetic research. ***States are not preempted by federal law from passing stronger, more privacy-protecting laws.***

Patient Consent

Only providers as defined in this statute (mostly individual practitioners) and "a person who receives a health record from a provider" must comply with M.S. 144.335. The M.S. 62J.55 requirement adds others, but does not include "health plan companies." Finally, "health records" and "medical records" are not defined in either statute.

Patient consent (M.S. 144.335 subd. 3a). "(a) A provider, or a person who receives health records from a provider, may not release a patient's health records to a person without a signed and dated consent from the patient or the patient's legally authorized representative authorizing the release, unless the release is specifically authorized by law..."

Other providers (M.S. 62J.55 (b)): "Providers and group purchasers shall treat medical records...in accordance with section 144.335..."

Exceptions for Researchers

Only researchers external to a health care institution must obtain patient consent, however, passive authorization (consent) to medical research by external researchers may be "established." The term "medical or scientific research" is not defined.

Internal researchers have access without patient consent (M.S. 144.335 subd. 3a(d)): "Notwithstanding paragraph (a), health records may be released to an external researcher solely for purposes of medical or scientific research only as follows:

(1) health records generated before January 1, 1997, may be released if the patient has not objected or does not elect to object after that date;

(2) for health records generated on or after January 1, 1997, the provider must:

(i) disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released; and

(ii) use reasonable efforts to obtain the patient's written general authorization that describes the release of records in item (i), which does not expire but may be revoked or limited in writing at any time by the patient or the patient's authorized representative;

(3) authorization may be established if an authorization is mailed at

least two times to the patient's last known address with a postage prepaid return envelope and a conspicuous notice that the patient's medical records may be released if the patient does not object, and at least 60 days have expired since the second notice was sent; and the provider must advise the patient of the rights specified in clause (4); and..."

Health Department Exempt

The Minnesota Department of Health (MDH) is permitted by state and federal law to collect patient data without patient consent. In addition, MDH is exempt from consent requirements for medical research. MDH may contract with outside researchers to conduct research using patient data. The MDH data collection rule was withdrawn in March 2003 due to public outcry, but the law remains in effect...and no rule is required. At least 137 million medical records have already been collected. To view statistics: <http://www.cchconline.org/medrecords.php>

Release of medical records to Minnesota Department of Health (M.S. 144.335 subd. 3b): "Subdivision 3a does not apply to the release of health records to the commissioner of health or the Health Data Institute under chapter 62J, provided that the commissioner encrypts the patient identifier upon receipt of the data."

Health Department research and data initiatives (M.S. 62J.301): "The commissioner of health shall conduct data and research initiatives in order to monitor and improve the efficiency and effectiveness of health care...[...]"

Information collection by MDH (M.S. 62J.301 subd. 4): "(a) The data collected may include health outcomes data, patient functional status, and health status. The data collected may include information necessary to measure and make adjustments for differences in the severity of patient condition across different health care providers, and may include data obtained directly from the patient or from patient medical records, as provided in section 62J.321, subdivision 1."

No consent (M.S. 62J.321 subd. 1(a)): "...Patient consent shall not be required for the release of data...pursuant to sections 62J.301 to 62J.42..."

Data used for medical research (M.S.144.053 subd. 1): "Status of data collected by commissioner. All information, records of interviews, written reports, statements, notes, memoranda, or other data procured by the state commissioner of health...shall be used solely for the purposes of medical or scientific research."

Thus far there are no patient consent requirements in the 2005 genetic research legislation introduced (numbers and partial titles):

- HF3/SF1 - Bonding Bill (Genetics research facility)
- HF434 - Biotechnology and Medical Genomics Research
- HF689/SF809 - Medical Genomics Research Facility