RESEARCH - - EXPERIMENTAL - - CONSENT REQUIRED

THE LAW

Each patient shall..."Have a right not to be subjected to **experimental research** without the **express and informed consent** of the patient and of the patient's guardian **after consultation** with **independent specialists** and the patient's **legal counsel**. Such proposed research shall first be reviewed and approved by the **institution's research and human rights committee** created under [s.51.61] sub. (4) and by the department before such consent may be sought. Prior to such approval, the committee and the department shall determine that research complies with the **principles of the statement on the use of human subjects for research** adopted by the **American Association on Mental Deficiency**, and with the **regulations for research involving human subjects required by the U.S. department of health and human services** for projects supported by that agency." § 51.61(1)(j), Wis. Stats. [Emphasis added.]

"(a) Each facility which conducts research upon human subjects shall establish a **research and human rights committee** consisting of not less than 5 persons with varying backgrounds to assure complete and adequate review of research activities commonly conducted by the facility. The committee shall be sufficiently qualified through the maturity, experience and expertise of its members and diversity of its membership to ensure respect for its advice and counsel for safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the committee shall be able to ascertain the acceptability of proposals in terms of commitments of the facility and federal regulations, applicable law, standards of professional conduct and practice, and community attitudes.

(b) No member of a committee may be directly involved in the research activity or involved in either the initial or continuing review of an activity **in which he or she has a conflicting interest**, except to provide information requested by the committee.

(c) No committee may consist entirely of persons who are officers, employees or agents of or are otherwise **associated with the facility**, apart from their membership on the committee.

(d) No committee may consist entirely of members of a **single professional group**.

(e) A majority of the membership of the committee constitutes a **quorum** to do business." § 51.61(4), Wis. Stats. [Emphasis added.]

"**'Research'** means a systematic investigation designed to develop or contribute to generalizable knowledge, except that it does not include an investigation involving only treatment records or routine follow-up questionnaires." DHS 94.02(38), Wis. Admin. Code [Emphasis added.]

"(1) An inpatient or residential treatment facility conducting or permitting research or drastic treatment procedures involving human subjects shall **establish a research and human rights committee** in accordance with 45 CFR 46, s. 51.61(4), Stats., and this section.

(2) The committee shall include **2 members who are consumers or who represent** either an **agency** or **organization which advocates rights of patients** covered by this chapter.

(3) The inpatient or residential treatment facility research and human rights committee shall designate a person to act as **consent monitor** who shall be authorized to validate informed consent and terminate a patient's participation in a research project or a drastic treatment procedure immediately upon violation of any requirement under this chapter or upon the patient's withdrawal of consent."

DHS 94.13, Wis. Admin. Code [Emphasis added.]

"(1) All proposed research involving patients shall meet the requirements of **s. 51.61(1)(j), Stats., 45 CFR 46, and this section**.

(2) No patient may be subjected to any experimental diagnostic or treatment technique or to any other experimental intervention unless the **patient gives informed consent**, the patient's informed consent is **confirmed by the consent monitor** and the **research and human rights committee has determined that adequate provisions are made to**:

(a) Protect the **privacy** of the patient;

(b) Protect the **confidentiality of treatment records** in accordance with s. 51.30, Stats., and ch. DHS 92;

(c) Ensure that **no patient may be approached to participate** in the research unless the patient's participation is **approved by the person who is responsible for the treatment plan of the patient**; and

(d) **Ensure** that the conditions of this section and other **requirements under this chapter are met**."

DHS 94.14, Wis. Admin. Code [Emphasis added.]

DECISIONS

DHS reviewed the following proposals and reached the following conclusions about them:

1. A proposal to solely **analyze existing medical records** to compare the costs of treating patients within a "medical home" to those not receiving their care through a "medical home." DHS determined that it **did not have jurisdiction** over the study because, under §51.61(j), Wis. Stats., DHS jurisdiction is limited to approving "research." As defined in DHS 94.02(38), Wis. Admin. Code, the term **"research" does not apply to studies solely analyzing existing data**. Given that the study was limited to analyzing existing data, it **did not require DHS approval**. (Access Community Health Centers Integrated Care Model Study, 1/16/13)

2. Two proposed interventions for **opioid dependency**. DHS identified two central concerns. One concern was that the **consent form did not include sufficient language** alerting participants to the **possible health risks** of the study, and that the study did not make adequate attempts to minimize these risks. DHS advised that this situation **created unacceptable risks** for these individuals and therefore did not comply with the requirements of §51.61, Wis. Stats., and 45 CFR 46. A second concern was that the study **lacked an adequate procedure** for **advising participants of their patient rights**, and had **not made provisions for a Client Rights Specialist** to process grievances. The researchers addressed the first set of concerns by **putting protocols in place to monitor and treat withdrawal symptoms**, and by adding to the consent form **more specific language regarding these risks**. The study addressed the second set of concerns by **providing subjects** with the DHS Client Rights Office **pamphlet**, "Client Rights and the Grievance Procedure for Community Services," and by agreeing to discuss its contents with each subject. The study also **identified two** individuals to serve as **Client Rights Specialists** for any complaints that arose during the study. Given that the **investigators addressed all of DHS's concerns**, the study received **DHS approval**. (Department of Family Medicine Drug Court Study, approved 2/11/13)

3. A proposal to establish a **DNA "biobank"** containing the **genetic material** of **individuals with alcoholic hepatitis**. The participants were receiving services from Mayo Clinic for mental illness, alcoholism, or drug dependency; however, the study was not investigating an intervention or treatment. The study was **solely examining** a **possible association between certain genes and clinical symptoms** of alcoholic hepatitis as reflected in participants' existing medical records. Subsection 51.61(1)(j) only requires DHS approval of "***experimental* research**." DHS 94.14, Wis. Admin. Code, refers to "research" refers as an "*experimental*…*treatment technique*" or an "*experimental intervention.*" Moreover, DHS 94.02(38) excludes studies "involving only treatment records or routine follow-up questionnaires" from the definition of "research." Given that the proposed study was **not investigating an "experimental treatment technique"** or **"experimental intervention**," it was found to be more akin to an "investigation involving only treatment records or routine follow-up questionnaires," and **thus exempted from the definition of "research"** under DHS 94.02 (38). Thus, DHS did not have jurisdiction over the study. However, it was noted that participants were still covered by the full range of patient rights with respect to any services they received from the clinic for mental illness, alcoholism, or drug dependency. (Mayo Clinic Alcoholic Hepatitis Study, 4/4/14)

4. A proposal to establish a **DNA "biobank"** for storing samples of the **genetic material of individuals with bipolar disorder**. After review, DHS concluded that, although participants would include people currently receiving outpatient services for mental illness, and who would undergo psychiatric evaluations within the study to confirm their diagnoses, the study was **not investigating an intervention** or **treatment** for mental illness, alcoholism, or drug dependency. The study was solely examining a possible association between variations in a specific gene and symptoms of antidepressant induced mania as reflected in participants' medical records. Subsection 51.61(1)(j), Wis. Stats., only requires DHS approval of "*experimental* research," and DHS 94.14, Wis. Admin. Code, refers to "research" as an "*experimental*…*treatment technique*" or an "*experimental intervention."* Moreover, DHS 94.02(38) excludes studies "involving only treatment records or routine follow-up questionnaires" from the definition of "research." Because the proposed study would not be investigating an "experimental treatment technique" or "experimental intervention," it was found to be more akin to an "investigation involving only treatment records or routine follow-up questionnaires," which is **exempted from the definition of "research"** under DHS 94.02 (38), Wis. Admin. Code. Thus, the study **did not require DHS approval** because it did not constitute "experimental research." However, participants were still covered by the full range of patient rights with respect to any services they received from the clinic for mental illness, alcoholism, or drug dependency, including any psychiatric evaluations, assessments, or diagnoses received as part of the study. Participants therefore had to be **notified** in the informed consent document **of their client rights** relating to evaluations, assessments, and diagnoses of mental illness. The study was also required to notify participants of their **right to file grievances** and the applicable procedure. (Mayo Clinic Bipolar Biobank Research, 4/4/14)

5. A proposal at the Wisconsin Resource Center (WRC) in which **inmates** were to be interviewed in light of their record of showing **improvement with respect to self-harm**. A threshold issue was whether individuals at WRC were "patients," which in turn determined whether the Client Rights Office (CRO) had jurisdiction over the study. Although the statutory language was somewhat unclear, in light of DHS 94.01(2) it was **determined that WRC fell under the jurisdiction of CRO** with respect to certain sections of § 51.61, including the right not to be subjected to "experimental research" under § 51.61(1)(j). Therefore, **if WRC was conducting experimental research** involving residents, **it would need DHS approval** and would need to follow the requirements of DHS 94.13 and DHS 94.14. However, CRO's jurisdiction is limited to "experimental research" studies, and WRC's proposed study would **solely interview individuals in light of their record** of showing improvement with respect to self-harm. This was found to be more akin to an "investigation involving only treatment records or routine follow-up questionnaires," which is exempted from the definition of "research" under DHS 94.02 (38), Wis. Admin. Code. Therefore, WRC **did not require DHS approval** because the study **did not constitute "experimental research"** as defined in the statute and administrative code. (Wisconsin Resource Center, 5/14/14)

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