

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

[None at this time.]

[See: "Introduction to Digest-Date Last Updated" page]