**Section 380.580 Research**

a) *No consumer shall be subjected to research or treatment without first obtaining his or her informed, written consent. The conduct of any experimental research or treatment shall be authorized and monitored by an institutional review board appointed by the executive director. No person who has received compensation in the prior 3 years from an entity that manufactures, distributes or sells pharmaceuticals, biologics, or medical devices may serve on the institutional review board*.

1) *The membership of the institutional review board shall* include, at a minimum:

A) Director of the Department of Public Health or designee;

B) Director of DHS-DMH or designee;

C) An academic faculty member of a college or university who is in a mental health field;

D) The DHS-DMH bureau chief of Evaluation and Services Research or designee;

E) Two additional persons with a background in ethics, policy development and research who may be from outside DHS-DMH or the Department; and

F) A representative from the Department's or DHS-DMH's legal services staff as a non-voting member.

2) *The operating procedures for the institutional review board shall be* jointly developed by the Department and by DHS-DMH and shall be made available to the public upon request. The operating procedures shall address:

A) The appointment protocol and tenure of the membership;

B) Conflict-of-interest policies;

C) The meeting schedule;

D) The application process, including university-initiated applications;

E) Informed consent requirements, which shall reference 45 CFR 46 (Protection of Human Subjects), Subparts B, C and D, and the Mental Health and Developmental Disabilities Confidentiality Act;

F) Requirements for progress reports; and

G) The review process and expedited review process.

3) *The review criteria for the institutional review board shall be* developed jointly by the Department and by DHS-DMH and shall include:

A) Voting procedures;

B) A categorization of risks inherent in the conduct of the research; and

C) A description of the categorical ratings that result from the review.

b) *No facility shall permit research or treatment to be conducted on a consumer, or give access to any person or person's records for a retrospective study without the prior written approval of the institutional review board. No executive director, or person licensed by the State to provide medical care or treatment to any person, may assist or participate in any experimental research on or treatment of a consumer, including a retrospective study that does not have the prior written approval of the board.* This *conduct shall be grounds for professional discipline by the Department of Financial and Professional Regulation*.

c) Following a formal review, *the institutional review board may exempt from ongoing review research or treatment initiated on a consumer before the individual's admission to a facility and for which the board determines there is adequate ongoing oversight by another institutional review board. Nothing in this Section* or the Act *shall prevent a facility, any facility employee, or any other person from assisting or participating in any experimental research on or treatment of a consumer, if the research or treatment began before the person's admission to a facility, until the board has reviewed the research or treatment and decided to grant or deny approval or to exempt the research or treatment from ongoing review.* (Section 3-116 of the Act)