

WAYNE STATE UNIVERSITY

Wayne State University Human Investigation Committee	
SUBJECT	State and Local Research Guidelines and Regulations
Section	
Form Date	03/20/07
Approvals	

Background

There are no broad statutes that address human subject research in Michigan. However, the Michigan Mental Health Code and the Michigan Public Health Code both reference the protection of human subjects in specific research contexts. Both codes specify that such research should comply with provisions of 45 CFR 46 (Common Rule). The following are statutes that have implications for research conducted in the state of Michigan. The law or statute that best protects participants takes precedence.

Michigan Mental Health Code: MCL §§ 330.1116 - 330.2004a

This statute references confidentiality of mental health patients whose information is used in outside research. Confidentiality of such information should be maintained. This statute includes mental health patients who are prisoners. (see [45 CFR 46.301(b)])

Michigan Public Health Code: MCL §§ 333.110 - 333.25211

- This broad statute's purpose is to protect and promote the public health. The research implications in this statute involve:
 - Information shared with the Department of Community Health in the conduct of a medical research project (including projects involving birth defects) is confidential (MCL §§ 333.2631 and 333.5721);
 - The prohibition of the use of a live human embryo, fetus, or neonate for non-therapeutic research if the life of the embryo, fetus or neonate is jeopardized by the research (MCL § 333.2685);
 - Research records pertaining to patients with HIV are confidential (MCL § 333.5131);
 - The establishment of reporting criteria for certain infections and/or communicable diseases. Mandatory reporting of these hold if they are discovered in the course of research (MCL § 333.5111)

- The requirement that written informed consent be obtained from a person or the legally authorized representative of the person be obtained before a pre-symptomatic or predictive genetic test is performed and that the individual understands the following:
 - The nature and purpose of the genetic test;
 - The effectiveness and limitations of the genetic test;
 - The implications of taking the genetic test including, but not limited to, the medical risks and benefits;
 - The meaning of the genetic test results and procedure for providing notice of the results to the test subject;
 - Who will have access to the sample taken from the test subject in order to perform the genetic test and the information from the test, and the test subject's right to confidential treatment of the sample and the information.

The Human Cloning Funding Prohibition Act: MCL §§ 333.26401 – 26406

- This Act prohibits the expenditure of state funds for the purpose of human cloning. It does not prohibit the use of state funds for scientific research that does not involve the use of human somatic cell nuclear transfer technology to produce a human embryo.
- See also MCL §§ 333.16274 and MCL 333.16275 of the Michigan Public Health Code for further information on the prohibition of private rights of actions and the definitions of human cloning, human embryo, human somatic cell, and human somatic cell nuclear transfer.
- See also MCL § 750.430a of the Michigan Penal Code which states that a person who intentionally engages or attempts to engage in human cloning is guilty of a felony and faces imprisonment of up to 10 years and /or a fine of up to \$10,000,000.

Age of Majority Act: MCL §§ 722.51 – 722.55

This act defines the age of majority and describes all of the duties, liabilities responsibilities, rights and legal capacity of persons 18 years of age or older.

Status of Minors: MCL §§ 722.1 – 722.6

- Emancipation of a minor may occur either:
 - By way of a court order; and by law under any of the following circumstances:
 - When a minor is validly married;
 - When a person reaches the age of 18 years;
 - During the period when the minor is on active duty with the armed forces of the United States;
 - For the purposes of consenting to routine, non-surgical medical care or emergency medical treatment when the minor is in the custody of a law enforcement agency and the minor's parent or guardian cannot be promptly located;

- For the purposes of consenting to his or her own preventive health care or medical care during the period when the minor is committed to the jurisdiction of the department of corrections only if the parent cannot be located.

Minor Consent: MCL § 333.5127 & MCL § 333.9132

- The consent to receive medical, surgical care, treatment or services by a hospital, clinic or physician that is executed by a minor who professes to be infected with a venereal disease or HIV is valid and binding. (MCL § 333.5127)
- A minor may consent to the provision of prenatal and pregnancy related health care or to the provision of health care for a child of the minor and shall be valid and binding as if the minor had achieved the age of majority. Health care means only treatment or services intended to maintain the life and improve the health of both the minor and the minor's child or fetus. (MCL § 333.91320)
- Wayne State University's (WSU) research consent policy and procedure allows the minor to consent for her child or fetus to participate in research, if inclusion of the child or fetus of the minor meets the criteria set forth in 45 CFR 46. Subpart B.201-206 & 45 CFR 46. Subpart D.401-409.
- The minor cannot consent for participation in research unless they meet the definitions of emancipated minor. The minor child must be offered the opportunity to assent to participate as set forth in 45 CFR 46.408(a). Parental permission must be sought prior to enrolling the minor in research at WSU, unless the research protocol meets the criteria for a waiver of parental permission as set forth in 45 CFR 46.408(c).

Child Protection Law: MCL §§ 722.621 – 722.638

- For research, this statute allows the Family Independence Agency to provide a person engaging in research pertaining to child abuse with information contained in the state's central registry, on the understanding that the person receiving such information will not disclose the identifying information without a family's prior consent. (§ 722.627)
- This statute also specifies who is required by law to report suspected cases of child abuse and neglect. It further delineates that the exposure of minors under 12 years of age to amphetamine production, and that the diagnosis of pregnancy or venereal disease in minors under 12 years of age are considered to be child abuse and must be reported. (§ 722.623) If a controlled substance, alcohol, or a metabolite of a controlled substance is found in the body of a neonate, it constitutes a reportable child abuse.
- When a research protocol is such that child abuse or neglect may be identified, the parent must be informed during the consent process that it will be necessary to report it to appropriate authorities, if warranted.

Mental Health and Substance Abuse Services- Rules: R330.1001 – 330.1059

- The Michigan Department of Community Health states that research initiated, conducted, or supported by the Department must be subject to the administrative rules, department policies and must follow federal guidelines.

Michigan Social Welfare Act: §§ 333. 21771

- This statute requires that abuse, neglect, or exploitation of adults be reported by a person who is employed, licensed, registered, or certified to provide health care, educational, social welfare, mental health or other human services immediately. If adult abuse, neglect, or exploitation is confirmed or suspected as a result of someone participating in a research project, the same reporting responsibilities apply.