1.0 Reason for Policy

The purpose of this policy is to explain how Minnesota Law affecting research is applied by the Human Research Protection Program. The research community is expected to follow all state or local regulations or laws when conducting research with human subjects.

2.0 Scope of Policy

This policy is University-wide. All components of the University of Minnesota and its healthcare components must adhere to State laws that affect research.

3.0 Policy Statement

The research community is expected to follow all federal regulations, which by definition do not supersede any state or local regulations or laws that also may apply. Minnesota law is silent on many
research related issues and the research community must extrapolate in some areas from laws that affect treatment decisions. Researchers are advised of particular applicability of Minnesota statutes through electronic email newsletters routinely sent by the Office for the Vice President for Research and through information on the HRPP web site. IRB committee members have training materials, prepared by the Office of the General Counsel (OGC), which address specific issues. Training sessions are held periodically to ensure that HRPP staff, IRB members and researchers are current with the legal requirements.

The HRPP has access to counsel through the OGC of the University of Minnesota. Any IRB questions related to research and State law should be reviewed by OGC.

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**Minnesota Laws**

**Reporting Requirements** (Minnesota Statute 626.556 and 626.557)
Under Minnesota law, professionals engaged in education, health care, social services and other professions are required to report known or suspected instances of child neglect or physical or sexual abuse. When research is likely to reveal this type of information, such as interviews about personal behavior, child-rearing practices, and discipline, or when talking to others about the child or specific familial relationships, both the parental permission form and the assent form should clearly indicate that the investigator is required to report known or reasonable suspicion of abuse or neglect of a child. Similar reporting requirements also exist when vulnerable adults are involved in research and a researcher learns or reasonably suspects the vulnerable adult has been subjected to maltreatment through abuse, neglect, or financial exploitation.

**Parental Consent for Minors** (Minnesota Statutes 144.341 – 347, and 524.5- 207)
Although Minnesota law does not specifically address the issue of parental consent for minors to participate in research, based on legal advice and established practice, the research community follows the rules that apply to parental consent for treatment. The consent of one parent is sufficient to provide treatment to a minor except where the minor is undergoing an abortion. Any study involving care or treatment to a minor in connection with an abortion would need the consent of both parents if they are living. Other studies may proceed with the consent of one parent under Minnesota law. However, the IRB still must determine whether consent of both parents is necessary when research is covered by 45 CFR 46, Part D.

Under Minnesota law, a minor who has a court appointed guardian may not receive experimental treatment of any kind without a court order.

**Consent by Minors** (Minnesota Statute 144.341,342, 343, 344, and 253B.03)
Minnesota law permits emancipated minors to give effective consent for any medical services. Emancipated minors are those living apart from their parents and managing their own affairs, minors who have been married, those who have borne a child, and those declared by a court to be emancipated. Also, minors may give effective consent without parental permission to receive services in connection with: pregnancy, sexually transmitted diseases, drug or alcohol abuse, Hepatitis B vaccination, and inpatient mental health care if the minor is age 16 or older. If a minor receives these services, including pregnancy testing, as part of a research study with parental/guardian consent, the study physician may
not inform the parent or legal guardian of the treatment/testing information without the minor’s consent unless failure to do so would seriously jeopardize the health of the minor.

Consent by minors for research participation may be valid under Minnesota law where the minor is emancipated or the research consists principally of providing treatment to the minor related to a condition for which the minor has authority to consent. However, because this issue is unsettled under state law, the IRB is generally advised to consult legal counsel and/or consider whether the research qualifies for a waiver of parental permission under federal regulations before approving such research based on minor consent only.

Consent for Incompetent Adults (Minnesota Statute 524.5-313, 144.291, 13.384)
Under Minnesota law, an incapacitated adult who has a court appointed guardian or conservator may not receive experimental treatment of any kind without a court order. Except for this requirement, Minnesota law does not address the issue of research participation by incapacitated adults. Based on legal advice and established practice, the research community follows the rules that apply to surrogate consent for treatment. Legally authorized representatives of incompetent or incapacitated adults are determined in the following order of priority: healthcare agent previously appointed by the individual through a health care power of attorney; spouse; parents; adult children; and finally, adult siblings.

As a matter of subjects’ protection, assent should be obtained from incompetent adults for research participation to the extent they are able to provide assent. Even where a legally authorized representative has consented to the research participation, an incompetent adult may not be included over his or her objection.

Clinical Drug Trials and Inclusion of Persons under a Stay of Commitment Order (Minnesota Statute 253B.095 Subdivision 1)
Under Minnesota Law, a person who has had a commitment hearing and is released by the court before a commitment order is issued, is prohibited from participating in a psychiatric clinical drug trial during the period of a stay of commitment unless the court specifically authorizes the participation. The statute states:

[D]uring the period of a stay of commitment, the court may allow the patient to give consent to participate in a specific psychiatric clinical drug trial if the treating psychiatrist testifies or submits an affidavit that the patient may benefit from participating in the trial because, after providing other treatment options for a reasonable period of time, those options have been ineffective. The treating psychiatrist must not be the psychiatrist conducting the psychiatric clinical drug trial. The court must determine that, under the circumstances of the case, the patient is competent to choose to participate in the trial, that the patient is freely choosing to participate in the trial, that the compulsion of the stayed commitment is not being used to coerce the person to participate in the clinical trial, and that a reasonable person may choose to participate in the clinical trial.

Labeling of Investigational Drugs (Minnesota Statute 151.212 subdivision 1; Minnesota Rule 6800.3400, subpart 1)
Minnesota regulations for labeling prescription drugs apply to investigational drugs; however, there is flexibility for labeling of investigational drugs due to the unique nature of investigational studies, particularly studies involving a placebo. Additional information regarding labeling requirements appears in policy 412A.
Disclosure of Health Records for External Research (Minnesota Statute 144. 295)
Minnesota law is more restrictive than HIPAA in certain respects regarding access to health records for research purposes. Researchers external to the University who obtain an IRB waiver of the HIPAA authorization requirement still must meet state law requirements (an authorization signed by patients permitting access to their records for research purposes generally) in order to access health records. IRB staff is knowledgeable about the differences between Minnesota law and HIPAA in the research context and applies the appropriate standard when reviewing research applications.

Gifts to Researchers (Minnesota Statute 151.461)
Under Minnesota law, practitioners with authority to prescribe drugs are prohibited from accepting gifts from drug manufacturers and wholesale distributors valued at more than $50 per year. There are certain exceptions including payments for consulting and honoraria. Consistent with this law and University policy generally, researchers may not accept gifts, such as finders’ fees or recruitment bonuses, paid by research sponsors or others to the researcher personally in connection with University research activity. This prohibition is reflected in IRB application forms.

Patients Bill of Rights (Minnesota Statute 144.651, subdivision 13)
There is a patients bill of rights under Minnesota law that affords hospital patients and residents of health care facilities certain rights, including, the right to refuse participation in experimental research. This provision does not preclude emergency research conducted in conformance with federal guidelines.

Minnesota Genetic Privacy Act (Minnesota Statute 13.386)
Minnesota law classifies genetic information as private data. The Minnesota Supreme Court has interpreted the definition of genetic information to include blood samples. Researchers must have written informed consent to collect, use, store or disseminate genetic information, including blood samples, for research.

4.0 Required approvals for this document

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<tr>
<th>Title</th>
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<tr>
<td>Executive Director</td>
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<td>Counsel to the IRB</td>
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5.0 Revision History

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<td>06/19/15</td>
<td>Revise language related to participation of persons under a stay of commitment order</td>
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<td>03/21/14</td>
<td>AAHRPP</td>
<td>09/02/14</td>
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<td>10/23/12</td>
<td>Update minor consent reference</td>
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<td>Update AAHRPP reference</td>
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To obtain a copy of a historical policy, e-mail at irb@umn.edu or call 612-626-5654