ASSEMBLY BILL NO. 578–COMMITTEE ON HEALTH AND HUMAN SERVICES

(ON BEHALF OF THE NEVADA SYSTEM OF HIGHER EDUCATION)

MARCH 26, 2007

Referred to Committee on Health and Human Services

SUMMARY—Prescribes the requirements for surrogate decision makers to give informed consent for certain human subject research. (BDR 40-275)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State: No.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets **[**~~omitted material~~**]** is material to be omitted.

AN ACT relating to public health; prescribing the requirements for surrogate decision makers to give informed consent for certain behavioral or medical research on behalf of human subjects who are incapable of giving such consent; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Sections 2-12 of this bill prescribe the requirements for certain persons to act as a surrogate decision maker to give informed consent to perform certain behavioral or medical research on behalf of a human subject who is incapable of giving consent. **Section 11** lists the persons who may act as surrogate decision makers in order of priority. **Section 12** prohibits a surrogate decision maker from being compensated for giving informed consent on behalf of a human subject.

Under existing law, a court-appointed guardian of a ward must obtain approval from a court before the guardian may authorize experimental treatment of the ward. (NRS 159.0805) **Section 13** of this bill provides an exception from the requirement of obtaining approval from a court if the guardian acts as a surrogate decision maker pursuant to **sections 2-12** of this bill.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 439 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 12, inclusive, of this act.

Sec. 2. ***As used in sections 2 to 12, inclusive, of this act, unless the context otherwise requires, the words and terms defined in sections 3 to 7, inclusive, of this act have the meanings ascribed to them in those sections.***

Sec. 3. ***"Emergency services and care" has the meaning ascribed to it in NRS 439B.410.***

Sec. 4. ***"Human subject" has the meaning ascribed to it in 45 C.F.R. § 46.102.***

Sec. 5. ***"Person" includes a government, a governmental agency or a political subdivision of a government.***

Sec. 6. ***"Research" means a systematic investigation, including, without limitation, development, testing and evaluation, designed to develop or contribute to generalized knowledge.***

Sec. 7. ***"Surrogate decision maker" means a person authorized pursuant to section 11 of this act to give informed consent on behalf of a human subject.***

Sec. 8. ***1. The Legislature hereby declares that behavioral and medical research relating to the cognitive impairment, lack of capacity, or serious or life-threatening disease or condition of human subjects is vital for the benefit of the residents of Nevada and must be undertaken with due respect for the preciousness of life and the right of each person to determine his participation in such research.***

2. The Legislature recognizes that, under certain circumstances, a person may not be able to give informed consent to participate in such research on his own behalf.

3. It is the intent of the Legislature to prescribe provisions governing the circumstances in which a surrogate decision maker may give informed consent on behalf of a human subject for the performance of such research.

Sec. 9. ***The provisions of sections 2 to 12, inclusive, of this act do not:***

1. Preempt any applicable state law which requires the disclosure of information to a person before the provision of medical treatment to the person for informed consent to the treatment to be legally effective.

2. Prohibit the provision of emergency services and care to a person to the extent that a hospital or physician is required or

authorized to provide such services under applicable federal or state laws.

Sec. 10. ***1. Except as otherwise provided in subsection 2, before a person performs behavioral or medical research relating to the cognitive impairment, lack of capacity, or serious or life-threatening disease or condition of a human subject who is incapable of giving informed consent to such research and who does not express any dissent or resistance to participation in the research, the person must obtain the informed consent of a surrogate decision maker on behalf of the human subject pursuant to sections 2 to 12, inclusive, of this act.***

2. A person shall not request the informed consent of a surrogate decision maker unless:

(a) The person performing the research has completed a program of training relating to the protection of human subjects; and

(b) The research is approved and monitored by an institutional review board pursuant to the provisions of 45 C.F.R. Part 46.

3. If a human subject, at any time after the commencement of the research, refuses to participate in the research or attempts to resist such participation, the person performing the research shall immediately cease the research involving that human subject.

Sec. 11. ***1. The authority to act as a surrogate decision maker to give informed consent on behalf of a human subject who is not receiving emergency services and care when the informed consent is sought may be exercised by the following persons in order of priority:***

(a) The attorney-in-fact of the human subject pursuant to a durable power of attorney for health care executed pursuant to NRS 449.800 to 449.860, inclusive;

(b) A conservator or guardian of the human subject who has authority to make health care decisions for the human subject;

(c) The spouse of the human subject;

(d) An adult child of the human subject;

(e) A custodial parent of the human subject;

(f) An adult sibling of the human subject;

(g) An adult grandchild of the human subject; or

(h) Another adult relative of the next closest degree of consanguinity to the human subject.

2. If there are two or more persons who are authorized to give informed consent on behalf of a human subject and those persons are in different orders of priority as set forth in subsection 1, the decision or the lack of decision to give consent of the person with the highest priority supersedes each person who has lower priority.

3. If there are two or more persons who are authorized to give informed consent on behalf of a human subject and those persons are in the same order of priority, the refusal to give consent or the lack of decision by one or more of those persons supersedes the consent given by another of those persons.

4. The authority to act as a surrogate decision maker to give informed consent on behalf of a human subject who is receiving emergency services and care when the informed consent is sought may be exercised by the persons identified in paragraphs (a) to (f), inclusive, of subsection 1. If there are two or more of such persons, the refusal to give consent by one or more of those persons supersedes any consent given by another of those persons.

Sec. 12. ***1. A surrogate decision maker shall not give informed consent on behalf of a human subject unless he:***

(a) Is provided with detailed information relating to the process for giving informed consent;

(b) Is provided with adequate information concerning the relevant procedures involved in performing the research; and

(c) Possesses reasonable knowledge of the interests of the human subject concerning such procedures.

2. The decision of a surrogate decision maker whether to give informed consent on behalf of a human subject must be based upon the health care instructions of the human subject, if any, or the interests of the human subject relating to such research, to the extent known to the surrogate decision maker. If the surrogate decision maker does not know the health care instructions or interests of the human subject, the surrogate decision maker shall consider the personal values of the human subject and make a decision in accordance with what the surrogate decision maker believes the human subject would have chosen if he were able to make a decision on his own behalf.

3. A surrogate decision maker may not receive compensation for giving informed consent on behalf of a human subject.

4. If a surrogate decision maker gives his informed consent on behalf of a human subject, the person performing the research and the surrogate decision maker shall, before the research is commenced:

(a) Certify in writing that both parties complied with the provisions of sections 2 to 12, inclusive, of this act; and

(b) Maintain a copy of the written certification.

Sec. 13. NRS 159.0805 is hereby amended to read as follows:

159.0805 1. Except as otherwise provided in ~~[~~subsection 2,~~]~~ ***subsections 2 and 4,*** a guardian shall not consent to:

(a) The experimental, medical, biomedical or behavioral treatment of a ward;

(b) The sterilization of a ward;

(c) The participation of a ward in any biomedical or behavioral experiment; or

(d) The commitment of a ward to a mental health facility.

2. ~~[The]~~ ***Except as otherwise provided in subsection 4, a*** guardian may consent to and commence any treatment, experiment or commitment described in subsection 1 if the guardian applies to and obtains from the court authority to consent to and commence the treatment, experiment or commitment.

3. The court may authorize ~~[the]~~ ***a*** guardian to consent to and commence any treatment, experiment or commitment described in subsection 1 only if the treatment, experiment or commitment:

(a) Is of direct benefit to, and intended to preserve the life of or prevent serious impairment to the mental or physical health of, the ward; or

(b) Is intended to assist the ward to develop or regain the ward's abilities.

4. The provisions of this section do not apply if a guardian gives informed consent to behavioral or medical research relating to the cognitive impairment, lack of capacity, or serious or life-threatening disease or condition of the ward pursuant to sections 2 to 12, inclusive, of this act.

Sec. 14. This act becomes effective on July 1, 2007.

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