PROPOSED REGULATION OF THE

NEVADA INSTITUTIONAL REVIEW BOARD

LCB File No. R159-05

December 20, 2005

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

AUTHORITY: §§1-25, section 7.3 of Assembly Bill No. 208 of the 73rd Session of the Nevada Legislature, chapter 489, Statutes of Nevada 2005, at page 2524 (NRS 630A.900).

A REGULATION relating to medical research; providing various aspects of a research proposal or study that the Nevada Institutional Review Board may control; creating the position of Executive Director; providing the manner by which decisions on a research proposal or study are to be communicated; providing that the Board may act as an institutional review board for a research study unconnected to the Board under certain circumstances; providing that the Board may cosponsor a research study; requiring a Board member who conducts research under the supervision of the Board to follow the same regulations and guidelines as other researchers; providing that the Board may select advisory members and consultants; providing that the Board may create advisory committees and appoint chairmen for those committees; providing the manner in which an advisory committee may review and approve a research proposal or study; allowing monetary compensation for research subjects under certain conditions; establishing the informed consent process for research subjects; allowing a researcher to amend a study without Board approval under certain circumstances; establishing certain requirements for a study; and providing other matters properly relating thereto.

Section 1. Chapter 630A of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 25, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 25, inclusive, of this regulation, unless the context otherwise requires, "Board" means the Nevada Institutional Review Board.***

Sec. 3. ***The Board hereby adopts by reference the ethical principles and guidelines contained in The Belmont Report, published by the National Commission for the Protection of***

Human Subjects in Biomedical and Behavioral Research, April 18, 1979. The report is available free of charge at the following Internet addresses:

1. <http://ohsr.od.nih.gov/guidelines/belmont.html>.

2. <http://www.fda.gov/oc/ohrt/IRBS/belmont.html>.

Sec. 4. *1. The Board will review all submitted research proposals involving human subjects before the research may begin and will approve only research proposals that meet the policies and regulations of the Board.*

2. The Board will oversee, review and control all aspects of the research studies approved, including, without limitation:

(a) Methods of identifying potential subjects;

(b) Methods for contacting potential subjects;

(c) Materials to recruit subjects and any proposed remuneration;

(d) Pilot studies;

(e) Proposals to use or provide stored bodily fluids, tissues or confidential data;

(f) Surveys and interview questions;

(g) The informed consent process and form;

(h) The protocol and summary of the research;

(i) Proposed changes to the research;

(j) Unanticipated problems involving risk to the subjects or others;

(k) Continuing reviews;

(l) Uses of investigational drugs and devices in emergencies; and

(m) Devices for humanitarian uses.

Sec. 5. *1. The Board will review all research proposals and studies in which the Board may be involved, including, without limitation:*

(a) Research sponsored by the Board; and

(b) Research which uses nonpublic information of the Board to identify or contact potential human subjects for research.

2. The Board will review the research proposals and studies set forth in subsection 1 even if the research is or will be conducted outside of this State.

Sec. 6. *The Board will appoint, by majority vote, a person to act as the Executive Director of the Board. The Executive Director shall oversee all activities of the Board. The Executive Director serves at the pleasure of the Board and may be removed from his position at any time by a majority vote of the Board.*

Sec. 7. *Regarding the research studies the Board oversees, reviews or controls, the Board may:*

1. Review all research projects that will involve human subjects before the contact or involvement of human subjects;

2. Approve, disapprove or require changes in any research;

3. Notify relevant governmental agencies and sponsors of approvals and disapprovals;

4. Ensure prompt reporting to the Board as well as to any sponsoring agency of unanticipated problems involving risks to subjects or others;

5. Ensure prompt reporting to the Board by investigators of any noncompliance with the Board or with any relevant statutes, regulations or policies;

6. Report serious or continuing noncompliance to the appropriate governmental agencies;

7. Suspend or terminate a previously approved project;

8. Conduct continuing reviews of ongoing research as well as any active monitoring that the Board considers necessary; and

9. Review and monitor the use of investigational drugs, biologicals, and devices outside of the context of research.

Sec. 8. *1. The Board will notify in writing a researcher who has submitted a research proposal or is conducting a research study under the oversight, review or control of the Board of any approvals, revisions, disapprovals or terminations.*

2. If the Board disapproves or terminates a research proposal or study, the researcher undertaking the proposal or study may request to present more information explaining why he believes the proposal or study should be approved or continued. If the Board accepts the request, the researcher may present the information in person or in writing.

Sec. 9. *The Board may agree to act as the institutional review board for a research study unconnected to the Board if the research study is being conducted by a researcher registered with the Board.*

Sec. 10. *1. In order to cosponsor a research study with another institution, the Board must be included as part of the approval authority for that study.*

2. Any research conducted by a member of the Board at another institution must include the Board as the approval authority for such research.

Sec. 11. *If a member of the Board wishes to conduct a research study under the oversight, review or control of the Board, the member must follow the same guidelines and requirements that other researchers are required to follow.*

Sec. 12. ***The Board may, by majority vote, select persons to act as advisory members to the Board. An advisory member cannot be counted in the quorum and cannot vote, but may participate in discussions and deliberations. An advisory member serves at the pleasure of the Board and may be removed from his position at any time by a majority vote of the Board.***

Sec. 13. ***The Board may, by majority vote, select such consultants as are necessary to provide services needed by the Board. A consultant serves at the pleasure of the Board and may be removed from his position at any time by a majority vote of the Board.***

Sec. 14. ***1. The Board may create an advisory committee to handle the initial oversight, review or control of a research proposal or study and to oversee the effective operation, policies and compliance of the proposal or study. The committee must only consist of advisory members of the Board.***

2. If an advisory committee is created, the Board will select a chairman from among the members of the Board to lead the advisory committee.

Sec. 15. ***Each chairman is responsible for adequately informing the Board of all information relevant to a particular research proposal or study. Each chairman shall designate at least one appointee to serve in his absence. Whenever a chairman is not available, the designated appointee will assume the responsibilities of the chairman.***

Sec. 16. ***1. Each advisory committee shall meet at least once a month and more frequently if needed.***

2. Each advisory committee is independent and cannot be overruled by another advisory committee. The Board may, by majority vote, overrule an advisory committee.

3. Two review processes exist under an advisory committee:

(a) Full committee review, which must occur at the monthly meeting of an advisory committee; and

(b) Expedited review, which must occur on a weekly basis as needed.

Sec. 17. *1. To approve a research proposal or study, the majority of the members of the Board who are present at a meeting must vote for the approval of the proposal or study.*

2. A member of the Board who is involved in any way in a research proposal or study that is being reviewed, or who has any other potential for conflict of interest, may not participate in the discussions or deliberations or attend the Board meeting regarding that proposal or study.

Sec. 18. *1. In order for a research proposal or study to receive expedited review, the proposal or study must be nominated for expedited review by the chairman of the advisory committee with initial oversight of the proposal or study.*

2. Research proposals or studies involving fetuses, pregnant women, minors, cognitively impaired persons, prisoners or any other group designated by the Board may not be reviewed through the expedited review process.

Sec. 19. *When reviewing a research proposal or study, the Board will consider, without limitation:*

1. The risks and benefits of the proposal or study;

2. The selection of subjects;

3. Privacy and confidentiality;

4. The informed consent process to be used;

5. Any necessary additional monitoring or safeguards;

6. Any necessary additional requirements for any population considered vulnerable or in need of special protection, including, without limitation, fetuses, pregnant women, minors, cognitively impaired persons and prisoners;

7. Any necessary additional requirements relating to drugs, investigational new drug applications, marketed drugs and radiopharmaceuticals; and

8. Any necessary additional requirements for devices or any investigational device exemptions.

Sec. 20. *Unless found to be coercive, the Board will not prohibit:*

1. Monetary compensation for participation in research studies; or

2. The mention of monetary compensation in advertisements soliciting participation in research studies.

Sec. 21. *1. The Board will require a research study to obtain informed consent by presenting information orally and then receiving written consent on a form approved by the Board, unless the Board determines that informed consent may be adequately obtained in another manner.*

2. A consent form must address, without limitation:

(a) The purpose of the research study;

(b) The procedures to be used in the research study;

(c) Potential risks or discomforts;

(d) The anticipated benefits from the research study;

(e) Alternative procedures to participation in the study;

(f) The confidentiality of any records kept during the study;

(g) Emergency care and compensation for injury;

(h) Contact information for any questions regarding the study;

(i) Issues related to participation in and withdrawal from the study; and

(j) The process for communicating new findings made during the course of the study.

3. The closing paragraphs of the consent form must read as follows:

You will be given a copy of this consent form to keep. By signing this consent form, you are not waiving any of your legal rights, claims or remedies. If you have any questions about such rights, claims or remedies, you may contact the Board.

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. By signing this consent form, I willingly agree to participate in this study. I have been given a copy of this consent form.

4. All consent forms must be approved by the Board and cannot be altered without the approval of the Board.

Sec. 22. *A researcher may not implement any amendments to a research study without the approval of the Board, except to eliminate an apparent, immediate hazard to the subjects.*

Sec. 23. *1. A researcher is required to report to the Board any unanticipated adverse event within 5 days after its occurrence, including an adverse effect that was anticipated by the research study but which has changed in nature, severity or frequency.*

2. The reporting required pursuant to subsection 1 includes, without limitation:

(a) Any procedural errors made during research;

(b) Breaches in confidentiality or privacy;

(c) Emotional disturbances;

(d) Noncompliance with federal or state laws or regulations;

(e) Noncompliance with the policies of the Board; and

(f) Any other problems occurring during research.

Sec. 24. *1. To remain active, all research studies must be reviewed at least once a year. The Board may require more frequent reviews as necessary.*

2. The researcher is responsible for ensuring that a research study is approved for continuation before a year has elapsed.

3. If approval for continuation of a research study has not been issued by the Board before the end of a year for which approval was given, the study must be terminated.

4. A research study which has been terminated pursuant to the provisions of subsection 3 may be continued if the study is reviewed and approved by the Board as a new research study.

Sec. 25. *1. All records from a research study must be kept for at least 3 years and:*

(a) For device studies, all records must be kept for at least 2 years after the later of:

(1) The date on which the investigation is terminated or completed; or

(2) The date that the records are no longer required for purposes of supporting a premarket application or a notice of completion of a product development protocol.

(b) For drug studies, all records must be kept for at least 2 years following:

(1) The date of approval of a marketing application for the drug studied; or

(2) The date the research study is terminated and any relevant institutional review board or governmental agency is notified of the termination.

2. All records must be maintained in a secure place with limited access for the research team.

3. Before transferring custody of or destroying any records, the researcher must contact the sponsor of the study, if applicable.

4. If participation in a research study may affect the medical care of a subject, a copy of the consent form of the subject must be placed in his medical chart.