ADOPTED REGULATION OF THE

NEVADA INSTITUTIONAL REVIEW BOARD

LCB File No. R154-05

Effective November 17, 2005

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

AUTHORITY: §§1, 2 and 3, 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.

A REGULATION relating to the Nevada Institutional Review Board; requiring the members of the Board to take an oath of affirmation; prescribing the election of officers of the Board; 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 and 3 of this regulation.
- Sec. 2. 1. In addition to taking the constitutional oath or affirmation of office set forth in Section 2 of Article 15 of the Constitution of the State of Nevada, each member of the Nevada Institutional Review Board will, as required pursuant to section 7 of Assembly Bill No. 208 of the 73rd Session of the Nevada Legislature, chapter 489, Statutes of Nevada 2005, at page 2524, take the following oath or affirmation:

I,, do solemnly swear (or affirm) that I am legally qualified to serve as a member of the Nevada Institutional Review Board and that I will well and faithfully perform all the duties of a member of the Nevada Institutional Review Board, on which I am about to enter, (if an oath) so help me God, (if an affirmation) under the pains and penalties of perjury.

- 2. An officer of the Nevada Institutional Review Board will administer the oaths or affirmations described in subsection 1.
- Sec. 3. The Nevada Institutional Review Board will elect its officers annually before

 June 30. The term of an officer begins on July 1 after the election and ends on June 30 of the

 succeeding year.

NOTICE OF ADOPTION OF PROPOSED REGULATION LCB File No. R154-05

The Nevada Institutional review Board adopted regulations assigned LCB File No. R154-05 which pertain to chapter 630A of the Nevada Administrative Code on October 12, 2005.

Notice date: 8/31/2005 Date of adoption by agency: 10/12/2005

Hearing date: 9/16/2005; 9/30/2005 **Filing date:** 11/17/2005

INFORMATIONAL STATEMENT

1. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary:

Public comment was solicited by sending notices of the workshop and hearings to: Office of the Attorney General 100 N. Carson St. Carson City, NV 89701, Washoe County Library, 301 South Center Street, Reno, NV 89505, New Hope Medical Center, 10120 S. Eastern Ave., Suite 100, Henderson, NV 89052, Board of Homeopathic Medical Examiners, 3626 Pecos McLeod, Ste. 5, Las Vegas, NV 89121; The Nevada Clinic 3663 Pecos McLeod, Las Vegas, NV 89121, and Las Vegas Clark County Library, 833 Las Vegas Blvd. North Las Vegas, NV 89101, Cancer Screening and Treatment Center of Nevada, 521 Hammill Ln., Reno, NV 89511.

Interested persons may obtain a copy of any written responses and the minutes of the workshop and hearing from the Nevada Institutional Review Board by mailing a request to the Board at 10624 S. Eastern Avenue, Suite A-006, Henderson, Nevada 89052, or by telephone to (702) 622-5000.

- 2. A statement indicating the number of persons who attended each meeting or workshop, testified at each hearing, and submitted written statements regarding the proposed regulation:
 - A. The number of persons who:

(a)	Attended each workshop:	September 16, 2005	0
(b)	Attended each hearing:	September 30, 2005	0
(c)	Testified at each workshop:	September 16, 2005	0
(d)	Testified at each hearing:	September 30, 2003	0
(e)	Submitted written comments		
	to the agency:		0

3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary:

Public comment was solicited by sending notices of the workshop and hearings to: Office of the Attorney General 100 N. Carson St. Carson City, NV 89701, Washoe County Library, 301 South Center Street, Reno, NV 89505, New Hope Medical Center, 10120 S. Eastern Ave., Suite 100, Henderson, NV 89052, Board of Homeopathic Medical Examiners, 3626 Pecos McLeod, Ste. 5, Las Vegas, NV 89121; The Nevada Clinic 3663 Pecos McLeod, Las Vegas, NV 89121, and Las Vegas Clark County Library, 833 Las Vegas Blvd. North Las Vegas, NV 89101, Cancer Screening and Treatment Center of Nevada, 521 Hammill Ln., Reno, NV 89511.

The public comment is summarized in section 1 above.

Interested persons may obtain a copy of any written responses and the minutes of the workshop and hearing from the Nevada Institutional Review Board by mailing a request to the Board at 10624 S. Eastern Avenue, Suite A-006, Henderson, Nevada 89052, or by telephone to (702) 622-5000.

4. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation proposed.

No changes were made to the regulations submitted to the LCB, following the hearing and workshop. Regulations were made available for public comment before sending to the Legislative Counsel Bureau due to time constraints in Sec. 17(2) of AB 208_EN, which required regulations to be adopted "on or before October 1, 2005." Following the workshop on September 16, 2005, the NIRB approved the regulations on September 28, 2005. The LCB sent R-154-05 on September 29, 2005, which was included with the Hearing on September 30, 2005. The Board of Homeopathic Medical Examiners approved the NIRB Regulations and R-154-05 following the Hearing on September 30, 2005. R-154-05 was approved by the NIRB on October 1, 2005.

5. The estimated economic effect of the adopted regulation on the business that it is to regulate and on the public. These must be stated separately, and each case must include: (a) both adverse and beneficial effects and (b) both immediate and long-term effects:

A. Estimated economic effect on physicians or other licensees:

It is estimated that this regulation has a negligible economic effect on physicians or other licensees.

(a) Adverse and beneficial effects:

There are no apparent adverse or beneficial economic effects of the regulation on licensed physicians.

(b) Immediate and long-term effects:

(c)

There are no apparent immediate or long-term effects of this regulation on licensed physicians.

B. Estimated economic effect on the public:

It is estimated that the proposed regulation to be adopted and amended will not have any significant negative or positive economic effect on the public.

(a) Adverse and beneficial effects:

There are no apparent adverse or beneficial effects to the public of this regulation.

(b) Immediate and long-term effects:

The temporary regulation has similar immediate and long-term effects for the public, which are stated immediately above.

6. The estimated cost to the agency for enforcement of the proposed regulation:

There is no cost to the Nevada Institutional Review Board for enforcement of the proposed regulation.

7. A description of any regulations of the state or government agencies that the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, the name of the regulating federal agency.

The regulation does not overlap or duplicate any regulations of other state or local government agencies. The regulations have similarities to sections in the Code of Federal Regulations for the Food and Drug Administration and the National Institutes of Health that reference institutional review boards.

8. If the regulation includes provisions that are more stringent than a federal regulation that regulates the same activity, a summary of those provisions.

Not applicable.

9. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the manner in which the money will be used.

Not applicable.