
INTRODUCTION

At the direction of the Executive Branch Audit Committee, we conducted an audit of the Nevada Institutional Review Board (NIRB). Our audit addressed the following four questions:

- ✓ What is NIRB's role?
- ✓ What services must NIRB provide?
- ✓ Is a state board the proper level to provide these services?
- ✓ If a state board is the appropriate level, is NIRB carrying out its duties efficiently and effectively?

Our audit focused on whether NIRB is operating effectively and timely submitting reports to the Board of Homeopathic Medical Examiners.

Agency's Role and Public Purpose

NIRB was established on July 1, 2005 to monitor clinical research on complementary and integrative medicines. NIRB consists of seven appointed members (See Appendix A). Complementary and integrative medicines are therapies that combine modern and alternative therapies for the treatment of disease or disability. The common use of complementary and integrative medicine typically occurs in the treatment of cancer. Patients often seek additional therapies (i.e. acupuncture or herbal medicine) to help manage side effects of modern cancer treatment, such as nausea, pain, and fatigue. See Exhibit I.

Exhibit I

Types of Therapies

Modern	Alternative	Complementary and Integrative
Therapies found to be effective through scientific trials (i.e. surgery).	Therapies that do not follow generally accepted medical methods and may not have a scientific explanation for their effectiveness (i.e. acupuncture).	Alternative medicine is used <u>along</u> with modern medicine to treat a disease or condition (i.e. acupuncture along with surgery to repair damage to a knee).

The federal government estimates 62 percent of adults in the United States are using some form of complementary and integrative medical therapy.

The state board is the appropriate level to provide this oversight. It provides a central point of contact for citizens and researchers seeking information regarding complementary and integrative medical therapy.

NIRB has no permanent staff. It is funded through donations generated by a non-profit charity, which raised about \$19,000 in calendar year 2005.

Scope and Objective

We use a risk-based approach when selecting agencies for an audit. We focus our resources on operational areas with the most opportunities for improvement. A preliminary survey involves understanding an agency's programs through interviewing staff, observing agency operations, reviewing laws, regulations, policies, procedures, agency records, strategic plans, budgeting and staffing levels, and other information on agency activities.

We reviewed and discussed the NIRB's procedures with its board members and the members of the Board of Homeopathic Medical Examiners. Additionally, audit staff evaluated the effectiveness of policies in effect and compared the documented procedures to a sample of other boards' and organizations' procedures.

Our audit focused on the following objectives:

- ✓ Can the NIRB enhance effectiveness?
- ✓ Can the NIRB provide timely reports?

We performed our audit in accordance with the *Standards for the Professional Practice of Internal Auditing*.

The Division of Internal Audits expresses appreciation to the Nevada Institutional Review Board, and the President and Executive Director of the Board of Homeopathic Medical Examiners for their cooperation and assistance throughout the audit.

Contributors to this report:

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Executive Branch Auditor IV

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Executive Branch Auditor I

Nevada Institutional Review Board Response and Implementation Plan

We provided draft copies of this report to Nevada Institutional Review Board officials for their review and comments. NIRB's comments have been considered in the preparation of this report and are included in Appendix B. In its response, NIRB accepted both recommendations. Further, Appendix C includes a timetable to implement our report's recommendations.

NRS 353A.090 specifies within six months after the Executive Branch Audit Committee releases the final audit report, the Chief of the Division of Internal Audits shall evaluate the steps the Agency has taken to implement the recommendations, and shall determine whether the steps are achieving the desired result. The Chief shall report the six-month follow-up results to the Committee and NIRB officials.

The following report contains our findings, conclusions, and recommendations.

Can the NIRB Enhance Effectiveness?

The Nevada Institutional Review Board (NIRB) should consider developing an annual plan for reviewing research. By developing a plan NIRB can more effectively formulate its activities and enhance effectiveness.

Formed in July of 2005, NIRB was established to review clinical research of complementary and integrative medicine. As a newly formed board, NIRB has not yet developed a plan to review research as stated in its mission. Additionally, at the time of this audit, the NIRB had not yet reviewed any research material.

NIRB should develop an annual plan identifying the number of research reports it intends to review and the timelines for completion. This would allow NIRB to organize its activities around deadlines and provide concrete review dates for researchers.

Stanford University Medical School is one of the largest research centers in the country. When staff monitor research, they first establish a plan that identifies topic guidelines and number of research reports to review. Stanford staff indicated this helped them operate more effectively by organizing their research review process while providing the researchers with deadlines.

Recommendation:

1. Establish an annual plan for reviewing research.

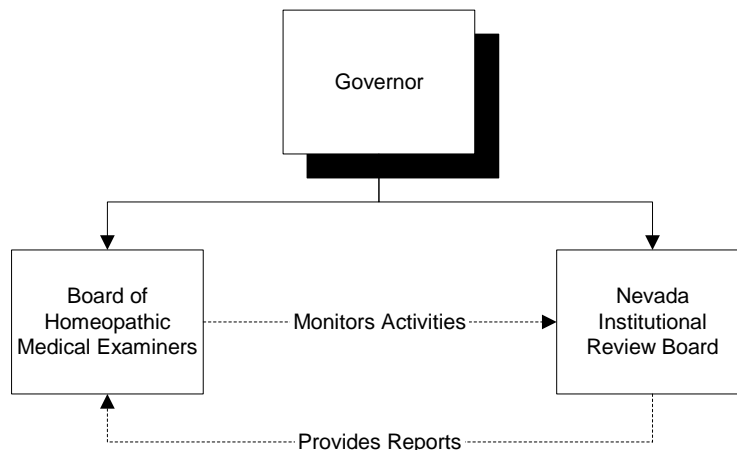
Can the NIRB Provide Timely Reports?

The Nevada Institutional Review Board (NIRB) should provide timely activity reports to the Board of Homeopathic Medical Examiners (Homeopathic Board). This would provide the Homeopathic Board with the information necessary to effectively monitor NIRB.

Statute requires NIRB to report on its activities to the Homeopathic Board on a quarterly basis. The Homeopathic Board is then required to monitor NIRB's activities. See Exhibit II

Exhibit II

Board Relationship



At the time of this audit, NIRB did not provide written reports on time for the quarter ended December 31, 2005¹. NIRB did provide a verbal report for this quarter on January 21, 2006; however, the Homeopathic Board contends only a written report will meet its requirements.

Recommendation

2. Submit written reports quarterly to the Homeopathic Board.

¹ A written report was submitted to the Homeopathic Board on March 17, 2006.

Appendix A

NIRB Additional Information and Terms

Creation of the Board and Current Members

The NIRB consists of 7 appointed members. Four are appointed by the Board of Homeopathic Medical Examiners. One member is appointed by the Governor. One member is appointed by the Majority Leader of the Senate, and one is appointed by the Speaker of the Assembly. The current members are: Dean Friesen, Roger Belcourt, Daniel Royal, Warren Evins, Ann O'Connell, Karen Hayes, Valerie Kilgore, and Karla Perez.

Complementary Medicine

Complementary medicine is the practice of combining alternative medicine (medical therapies that are not considered to be part of modern medicine and may not have had their effectiveness proven by scientific study) with modern forms of medicine for the treatment of disease. It is any treatment or practice that is not considered to be standard care.

Integrative Medicine

Integrative medicine is a total approach to care that involves the patient's mind, body, and spirit. It combines modern therapies with complementary therapies that are shown to have the most promise.

Appendix B

NIRB

Response and Implementation Plan

Appendix B

NIRB

Response and Implementation Plan

We would like to express our appreciation to the Auditors for their professionalism and patience with our “new” organization.

Exception is noted that you have listed eight board members, one of which had resigned as of January 25, 2006, that member being Valerie Kilgore.

The Audit report presented to you includes two recommendations as follows, with our responses as sub-paragraphs to each:

1) Establish an annual plan for reviewing research.

Response: The NIRB had made great progress in a remarkably short time in developing its research process, its ten committees and chairpersons for review of applications, pertinence, process, controls and protocols, etc. all of which are essential components of a high-quality Review Board. As noted by the Auditors, the NIRB was only formed as of July 1, 2005 and was in the process of completing its organization and planning processes when it was abruptly terminated by the interference of the Board of Homeopathic Medical Examiners (See Attachment to this Appendix B labeled Appendix B-1)

2) Submit written reports quarterly to the Homeopathic Board as required by statute.

Response: Written reports have been available to the BHME, including the complained about report as of December 31, 2005. It should be noted that the BHME was established to “supervise” the fledgling NIRB. At no time or in any fashion did the BHME provide “leadership” counseling or any constructive guidance as to the type of report they would like to receive from the NIRB. Efforts to use that Board's own reports as examples was futile, as they are well known to be extremely deficient in their own reporting and record-keeping.

Reports were also furnished to the Board of Medical Examiners (“BME”) and Board of Osteopathic Medical Examiners (“BOME”) as required by statute via email. An oral presentation was made to the BOME in January 2006. The BHME did not receive the NIRB report

at its January 21, 2006 meeting because the BHME failed to approve the agenda on where the report was to be presented. It was subsequently sent to the BHME's Executive Director, Marylou Heacock, via email and letter. No oral presentation was made to the BME in January 2006 because their meeting was not scheduled until March 2006.

Submitted By:
Nevada Institutional Review Board

A handwritten signature in black ink that reads "Robert K. Gentry". The signature is written in a cursive style with a large, stylized initial 'R'.

By Robert Gentry, Executive Director

Appendix B – 1

**NIRB
Response and Implementation Plan**

**Comments re Actions of the Board of
Homeopathic Medical Examiners**

The actions of the Board of Homeopathic Medical Examiners in its assigned role of supervising the NIRB can only be characterized as selfish efforts of multiple individuals seeking personal benefits. The board members routinely refused to accept or make efforts to understand facts presented to them. Dr. David Edwards, current President of the BHME, repeatedly made statements during BHME Meetings such as: (1) “I do not understand the NIRB”; and (2) “I do not know why we have the NIRB.”

Efforts to control the NIRB in order to influence project studies and protocols to benefit members and friends of the BHME board members have been well documented and made available to the State’s Attorney General’s Office.

In summary,

1. Earlene Forsythe and others have used their personal relationship with the Governor to persuade him to withdraw his appointment of Dean Friesen to the NIRB. By applying a standard not applied to any other Governor appointed Member of any other state board, the Governor declared Dean J. Friesen to be **“OVER QUALIFIED”**.
2. The BHME has withdrawn all (four) of its original appointments to the NIRB and failed to implement new appointments with qualified individuals. Those named by that Board as new nominees are not of the experience or stature of those withdrawn. Two of those nominees are actively involved in the personal conflicts of interest (Fuller Royal and Earlene Forsythe) and the others are subject to pressures of those two in those conflict efforts.
3. The NIRB is effectively in mothballs as the result of the BHME actions and the Governor’s action. These actions are a direct affront to the legislative intent in passing AB 208. In a letter directed to

Note: The attorney generals office determined that Dr. Friesen was not qualified to be a lay person on the board.

Paul Townswnd, Legislative Auditor dated March 14, 2006 Senator Schneider stated:

“On February 22, 2006, the Legislative Commission approved my request to conduct a performance audit of the Nevada State Board of Homeopathic Medical Examiners (“BHME”). At the time of my request, I submitted a letter documenting a couple of my concerns, which involve possible financial malfeasance and procedural misconduct. These problems began, and have continued to escalate, since the passage of AB 208 during the 2005 Legislative Session. AB 208 contained an amendment, Amendment 195, which I sponsored to create the Nevada Institutional Review Board (NIRB). My concerns include, but are not limited to, the facts that the BHME was insolvent at the time the NIRB was placed under its ‘supervision,’ the BHME has been operating in a dysfunctional manner, the BHME lacks an adequate check and balance system to monitor itself, and thus, the BHME is not capable of supervising another board.”

Submitted By:
Nevada Institutional Review Board



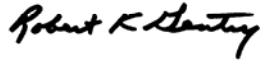
By Robert Gentry, Executive Director

Appendix C

**NIRB
Response and Implementation Plan**

The suggestions of the audit report would normally be simple to implement within a six-month time period; however as the supervising board (BHME) is disorganized and dysfunctional, and the NIRB has effectively been dismantled, no implementation of the suggestions is conceivable under the present circumstances.

Submitted By:
Nevada Institutional Review Board



By Robert Gentry, Executive Director

Appendix C

Time Table for Implementing Audit Recommendations

In consultation with the NIRB, the Division of Internal Audits attempted to categorize the recommendations into timeframes. The NIRB has indicated in their response that they are unable to implement the recommendations at this time (see Appendix B).

Recommendations with an anticipated implementation period.

<u>Recommendations</u>	<u>Time Frame</u>
1. Establish an annual plan for reviewing research. (page 4)	a
2. Submit written reports quarterly to the Homeopathic Board as required by statute. (page 5)	a

^a The NIRB has indicated it will be unable to implement any recommendations at this time.