

Kenny C. Guinn, Governor

Dean J. Friesen, Pharm. D., *President*

Roger M. Belcourt, M.D., M.P.H., *Vice President*

Daniel F. Royal, D.O., H.M.D., J.D., *Sec-Treasurer*



Warren H. Evins, M.D., Ph.D., *Member*

Ann O'Connell, *Member*

Karen Hayes-King, *Member*

Karla J. Perez, *Member*

**STATE OF NEVADA
NEVADA INSTITUTIONAL REVIEW BOARD**

MINUTES

Telephone Meeting of the Nevada Institutional Review Board

Friday, March 10, 2006 at 8:07 a.m.

Held at:

NEW HOPE MEDICAL LLC

Eastern Office Park

10120 S. Eastern Ave., Suite 100

Henderson, NV 89052

1. CALL TO ORDER.

a. Dean Friesen called the meeting to order @ 2:07 p.m. Roll call and determination of a quorum. Members present: Dean J. Friesen, Pharm.D., Daniel F. Royal, D.O., H.M.D., J.D., Ann O'Connell, Warren Evins, M.D., Ph.D., Roger M. Belcourt, M.D., M.P.H. Staff Present: Robert Gentry, *Executive Director*, Jim Smith, *Deputy Attorney General*. Members absent: Karen Hayes-King, Karla Perez.

b. Approval of the agenda.

Motion: Ann O'Connell moved to approve the agenda.

Second: Daniel F. Royal.

Action: Passed unanimously.

2. APPROVAL OF MINUTES:

Motion: Ann O'Connell moved to approve the minutes from 2-24-06.

Second: Daniel F. Royal.

Action: Passed unanimously.

3. EXECUTIVE BUSINESS

a. President's Report.

i Dr. Dean Friesen reported on recent events in which the Governor asked for Dr. Friesen's resignation on Friday, March 3, 2006. Dr. Friesen refused to resign. Dr. Daniel Royal submitted two letters to Keith Munro, Deputy Chief Counsel to the Governor, in behalf of the Nevada Institutional Review Board. The decision was reversed when Dr. Friesen received a phone call from Mr. Jim Spencer, Senior Deputy Attorney General from northern Nevada, on Thursday, March 9, 2006. Mr. Spencer apologized to Dr. Friesen, told him that the attorney general's opinion regarding his eligibility to serve as the Governor's appointee was being withdrawn, and that he was no longer under a "cloud of suspicion."

Dr. Royal suggested that the recent withdrawal of opinion from the attorney general's office may be unprecedented. Dr. Friesen also thanked the LCB (Legislative Counsel Bureau) for its help.

- ii Dr. Friesen discussed his response to the Homeopathic Board. Specifically, he addressed the issue of the Homeopathic Board's resignation letter received from Valerie
- iii Dr. Friesen discussed recent letter writing campaign by Mr. Joe Brown. Two manufacturers have attempted a takeover of the NIRB.

b. Executive Director's Report. Mr. Robert Gentry recently received a telephone call from a clerk in the unemployment office regarding Ms. Nancy Lucas. Ms. Lucas maintains that she continues to work for the board, she is a "whistleblower," and she could not have been terminated because this required board action. Mr. Gentry informed the clerk that Ms. Lucas had been terminated, she could not be a "whistleblower" because there had been no wrongdoing, and he disagreed with Ms. Lucas's statement that she could not have been terminated without board action. Mr. Gentry then read the original letter sent to Ms. Lucas on November 16, 2005 terminating her employment demanding the return of all NIRB property from Dr. Dean Friesen. This letter was sent via certified mail to her residence and the Nevada Clinic, where it was signed for, and posted on her door.

Motion: Dr. Daniel Royal moved that the board ratify the letter sent to Ms. Lucas terminating her employment on November 16, 2005.

Second: Roger Belcourt.

Discussion: Daniel F. Royal noted that, by Ms. Lucas filing a restraining order against Dr. Friesen, that she could no longer be an employee of either the Nevada Institutional Review Board or the New Hope Medical clinic. The Henderson Police informed Ms. Lucas of this fact before she filed for a restraining order. Dr. Warren Evins questioned whether Ms. Lucas's contract was temporary. Dr. Royal explained that Ms. Lucas's contract was to have been first reviewed by Ned Reed, Deputy Attorney General to the board. Ann O'Connell also noted that Ms. Lucas was aware of the fact that she would only be compensated as monies became available.

Action: Passed unanimously.

Motion: Dr. Daniel Royal moved to authorize Mr. Gentry to respond to the Nevada employment office regarding the employment of Ms. Lucas.

Second: Ann O'Connell.

Action: Passed unanimously.

Mr. Gentry discussed his efforts to obtain the return of board property from its former Secretary-Treasurer, Valerie Kilgore. Mr. Gentry has attempted to contact Ms. Kilgore by mail, email, fax, and phone. On February 28th, Mr. Gentry left a message on Ms. Kilgore's phone. She returned his phone call the following day and promised to send them. The items in question the possession of Ms. Kilgore include correspondence letters with Ms. Lucas, CD recordings of board meetings, bank financials, and other correspondence unknown to us. On February 29th, Ms. Kilgore responded by phone and promised to return the requested items the following day. To date, Ms. Kilgore has failed to return any NIRB property as requested. Mr. Gentry recommended that the board authorize its deputy attorney general to formalize a letter to Ms. Kilgore. Dr. Daniel Royal suggested Mr. Smith also send a copy of his letter to the Homeopathic Board where Ms. Kilgore is serving a member.

Motion: Dr. Roger Belcourt moved to authorize Mr. Jim Smith to send a letter in behalf of the board to Ms. Kilgore demanding a return of all NIRB property and to send a copy of the letter to the Homeopathic Board where she is serving as a member.

Second: Dr. Daniel Royal.

Action: Passed unanimously.

- c. UUUU Vice President's Report. No report.
- d. Secretary's Report. Dr. Daniel Royal noted that Mr. Robert Gentry had been excluded from the minutes on 1-20-06 and 2-03-06 as having attended the meeting as staff previously approved. He requested permission from the board to make these corrections, along with correcting a grammatical error in the 2-03-06 minutes, item 7, from "him appointment" to "his appointment."

Motion: Dr. Warren Evins moved to approve changes in the minutes suggested by the Secretary for the dates of 1-20-06.

Second: Ann O'Connell

Action: Yea: Dr. Friesen, Dr. Royal, Ann O'Connell, Roger Belcourt. Dr. Evins abstained because he was not present at the 1-20-06 meeting.

Motion: Dr. Warren Evins moved to approve changes in the minutes suggested by the Secretary for the dates of 2-03-06.

Second: Ann O'Connell

Action: Passed unanimously.

Motion: Dr. Warren Evins moved that the board approve Dave Rich to make changes to the NIRB website as required from time to time by our board.

Second: Ann O'Connell.

Action: Passed unanimously.

- e. Treasurer's Report. Karen Hayes-King asked Dr. Dean Friesen to request in her absence that the board maintain its procedures for check writing and accounting as previously approved. Ann O'Connell said the board had previously approved for two signatures to only be required for checks >\$700. Dr. Daniel Royal reminded the board that Dr. Warren Evins had previously requested the board to have two signers on all checks. Mr. Bob Gentry confirmed this was in the minutes of February 3, 2006, item 6. Dr. Evins said Mr. Gentry had explained to the board that the bank would have a difficult time distinguishing between checks that required one signature and those that required two signatures. Ms. O'Connell agreed that this would, in fact, be the case and the bank would not monitor it.

4. LEGAL TOPICS

- a. Calling a Meeting. Dr. Daniel Royal requested the board consider other options for calling a meeting, in addition the President. Dr. Warren asked about time notifications for a meeting. Dr. Royal said that time notification would not change and that three (3) days would still be required and the day of the meeting is not included in the time calculation. Dr. Royal noted that other boards do allow for a majority of its members to call a meeting and that the item out of the ordinary would be allowing for two board members to call a meeting. Dr. Evins asked about postings for the meetings. Dr. Royal said that the Executive Director would respond to those members calling a meeting. He further noted that postings needed to be done at three other locations in addition to the meeting location. Dr. Royal also advised that certificates of posting should also be sent along with the notices to confirm that such postings had actually occurred.

Motion: Ann O'Connell moved that, in addition to allowing the President to calling a meeting, the board allow a meeting to be called by either two officers of the board or four members of the board.

Second: Roger Belcourt.

Action: Passed unanimously.

- b. Investigational research application. Dr. Daniel Royal discussed options for applications. Applications can be used from independent contract sources. Dr. Friesen noted that the board cannot charge fees, but it can ask for donations. Dr. Friesen asked that item 4(b) be combined with 5(a).
- c. Revocation of waiver of conflict of interest. Dr. Daniel Royal suggested the board consider revoking its waiver previously provided to its former deputy attorney general, Ned Reed. Mr. Jim Smith requested that Mr. Reed first receive notification before this item be discussed. Dr. Dean Friesen mentioned that Mr. Reed was not present when the initial waiver was discussed. Dr. Royal informed the board that when a conflict of interest is to be waived by two parties, both parties must consent to the waiver, the Homeopathic Board has not waived the conflict, and thus, the board's waiver is ineffectual. Item to be moved to subsequent agenda after notice first provided to Mr. Reed.

5. ADMINISTRATIVE BUSINESS.

- a. Confidentiality. Continued from 4(b). Dr. Dean Friesen discussed the need to protect the details of applications submitted to the NIRB for approval and make them confidential. He stated this was based on three items: (1) confidentiality of patient identification protected under HIPPA; (2) confidentiality of procedure, where protected information might be revealed; and (3) intent or confidentiality of what the research investigator hopes to accomplish. Mr. Jim Smith stated this could also be proprietary information. Dr. Daniel Royal added it could be trade secret as well. Mr. Smith informed the board that the public records law would require everything to open to the public unless expressly confidential. He suggested that the application process define the parameters of the application so that the public was aware of what was open and what was closed. Thus, Mr. Smith recommended that the board begin defining its parameters and that a regulation eventually be adopted for this purpose. However, Dr. Friesen inquired as to whether the board could function to protect information until a regulation was adopted. Ann O'Connell asked if some research should be done into the areas of the law that would require confidentiality to be maintained such as confidentiality agreements between employers and employees. Ms. O'Connell requested Mr. Smith to do research in this area. Mr. Smith stated this could be done, but that this was a complicated area because of the public records law. Ms. O'Connell suggested that there was already language available in the statutes that could be used. Dr. Daniel Royal referred the board to NRS 332.025(5) and NRS 600.030(5), which describes "proprietary" and "trade secret" information, respectively. Dr. Royal suggested that the full application be reviewed by the board, but that a redacted version be made available to the public on the website. Mr. Smith stated that, eventually, the board would likely wish to have such procedure put into a regulation. Dr. Warren Evins expressed the desire to allow our committee chairmen and committee members to have access to the information in the applications. Dr. Friesen reported that, in a recent conversation he had with an independent contractor, that they are now going back through their applications and put them into compliance with HIPPA regulations. This is a fluid process that is continually evolving. Mr. Smith asked whether the board already had an application. Dr. Friesen responded that the board has the option of using an existing application for independent contractors. Mr. Smith agreed.

Dr. Roger Belcourt left the telephone meeting at approximately 9:00 a.m.

Motion: Daniel F. Royal moved to make all NIRB applications confidential insofar as they contain proprietary, trade secret, or confidential patient information and, once approved, provide only a redacted portion be made available for public review.

Second: Ann O'Connell.

Action: Passed unanimously.

- b. Approval Process. Continued from 4(b). Dr. Dean Friesen reviewed the flow chart for application approval. Applications are initially reviewed in the following order: Scientific Advisory Committee, NIRB Committees, Executive Director, and Operations. Research projects can be monitored by contract services with reports coming back to our board. For example, Western Institutional Review Board has over 2000 employees. Dr. Friesen presented two other IRBs with equally good reputations: Schulman (Ohio) and Chesapeake (Maryland). Using an outside contract service will help provide an arm's length relationship. This will also allow us to use without being subject to federal standards. Dr. Friesen suggested an application cost of \$6,000, with fee of \$1,500 being paid to an outside service agency. Dr. Friesen recommended Dr. Evins, Dr. Royal, and himself to be on the Scientific Advisory Committee. The regulations require the Scientific Advisory Committee its members to be "scientific." Dr. Daniel Royal stated that an individual is a layperson, even though trained and educated in science, so long as such a person is not licensed. Dr. Friesen noted that the Scientific Advisory Committee must also be composed from members of the board.

Motion: Daniel F. Royal moved to appoint Dr. Dean Friesen, Dr. Warren Evins, and Dr. Daniel Royal as members of the Scientific Advisory Committee.

Second: Ann O'Connell.

Action: Passed unanimously.

Motion: Ann O'Connell moved to appoint Dr. Warren Evins be chairperson of the Scientific Advisory Committee.

Second: Daniel F. Royal.

Action: Passed unanimously.

- c. Application Fee. Continued from 4(b). Dr. Dean Friesen discussed the fact that the board at this time cannot charge a fee, but it can assess a donation. Dr. Warren Evins asked whether a compulsory donation would be considered a fee. Ann O'Connell asked Mr. Smith whether this situation was similar to a politician obtaining a donation versus an honorarium for speaking to a group. Mr. Smith stated he believed the research community wants this board to provide them with a forum for certain kinds of research and that they would be willing to pay a donation. In addition, Mr. Smith said a donation should be fine because the board was not providing a service but rather a forum for research. Dr. Friesen stated that the primary investigator's license should also be included with the application and that such investigator must be licensed in Nevada. Dr. Daniel Royal mentioned that the fee schedule for Western IRB has numerous fees in addition to the application fee. In addition, Dr. Royal stated the Office of Human Research Protection Program has certified the three IRB contract services presented today. Dr. Friesen said the three IRBs presented today were recommended by NIH consultants as representing IRBs with the highest standards in the nation.

Motion: Daniel F. Royal moved to make \$6000 the initial donation for application submission.

Second: Ann O'Connell.

Action: Passed unanimously.

- d. Committees and Committee Chairpersons. Ten (10) committees presented at previous meeting on February 24, 2006 reviewed. These committees, and their proposed committee chairpersons, include: Lifestyle Evaluation (Ed Fujimoto, Ph.D.), Scientific Methodology and Evaluation (Lee Berk, Ph.D.), Legal and Governmental Affairs (Dr. Daniel Royal), Medical Statistics and Bioethics, Socio-Economic Impact (Bob Cooper, Director of Development for the City of Henderson), Scientific Concepts (Dr. Dean Friesen), Interprofessional Relations (Kathryn Craven, Pharm.D.), Commercial Impact, Development and Public Relations (Tim Bolen), and Education and Certification (Ronald Wempen, D.O.). Dr. Dean Friesen suggested that the foregoing individuals be

approved as committee chairpersons. Dr. Warren Evins asked whether the board had previously requested a curriculum vitae (CV) be submitted before approving a committee chairperson for appointment. Dr. Daniel Royal stated that, to date, he had only received CV's from Dr. Fujimoto, Dr. Berk, Dr. Wempen, Dr. Royal, and Dr. Friesen and that these had been forwarded to the board members. Ann O'Connell asked for time to review the CVs submitted for the proposed committee chairpersons.

Motion: Daniel F. Royal moved that the ten (10) committees be approved

Second: Ann O'Connell.

Action: Passed unanimously.

Dr. Royal mentioned that one committee chairperson the board could approve was Dr. Friesen, since the board members already knew him. In addition, Dr. Royal reminded the board that he, Dr. Royal, had already been previously approved at a prior meeting. Ms. O'Connell expressed a desire to approve all committee chairpersons at one time and to do so when more members were present. Dr. Royal questioned Jim Smith whether CVs should be kept confidential. Mr. Smith stated if a public board is using it, it becomes a public record. Ms. O'Connell asked Mr. Smith if he could provide more information on this subject to the board at its next meeting. Mr. Smith said the board needed to make it clear to its committee chairpersons that they would be acting in a public sense.

- e. Treasurer's duties and responsibilities. Tabled for future meeting until after the return of Karen Hayes-King, Treasurer.
- f. Executive Director Change. Dr. Daniel Royal stated that, in the event Dr. Dean Friesen was to be removed as President, the board could have a contingency plan to have Dr. Dean Friesen moved to Executive Director. No action taken.

- 6. PUBLIC COMMENT. None. Dr. Dean Friesen asked Jim Smith if he had anything to present. Mr. Smith stated that a place could be included for him to report at a future meeting so that notice to the public could be fairly given. He reminded the board to also provide more notice to the public in its reports for its next meeting.

Motion: Ann O'Connell moved the meeting be adjourned.

Second: Daniel F. Royal

Action: Passed unanimously.

- 7. ADJOURNMENT. Meeting adjourned at approximately 9:42 a.m.

- 8. NEXT MEETING DATE: March 24, 2006.