Vaccines, Blood & Biologics

Nevada Institutional Review Board

July 11, 2007

By Certified Mail - Return Receipt Requested

Anne O'Connell, President
Nevada Institutional Review Board
7225 Montecito Circle
Las Vegas, Nevada 89120

Dear Ms. O'Connell:

This letter describes the results of a Food and Drug Administration (FDA)) inspection of the Nevada Institutional Review Board (NIRB) that concluded on January 23, 2007. FDA Investigator Anthony Keller spoke with you via telephone and met with Fleming Fuller Royal, M.D., a current NIRB member, and Dean J. Friesen, PharmD, the former NIRB president, while he conducted an inspection of the NIRB to determine if the NIRB's procedures for the protection of human subjects comply with FDA regulations published in Title 21, Code of Federal Regulations (CFR), Parts 50 and 56. The inspection is part of FDA's Bioresearch Monitoring Program that includes inspections designed to review IRB operations for clinical studies of investigational products, and for the protection of human subjects.

Based upon the results of the inspection we note the following.

NIRB's solicitation for donations (http://www.nevadainstitutionalreviewboard.com/pdfs/NIRB_Donations.pdf) Web page states the NIRB will raise the level of health care in Nevada by making stem cells (nonembryo) available to all Nevadans. According to a State of Nevada Board of Homeopathic Medical Examiners 2006 legislative report, "The NIRB met December 13, 2006, and began a reorganization process. Researchers who have submitted requests to the NIRB to conduct research in stem cell therapy and new cancer therapies are currently awaiting permission from the NIRB to proceed." Stem cells for use in research conducted on human subjects are a biological product under section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. § 262(i)], applicable to the prevention, treatment, or cure of a disease or condition in human beings. Stem cells also are a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C.

§ 321(g)], in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Therefore, NIRB reviews of clinical investigations involving stem cell therapy in humans are subject to federal regulation governing the operation and responsibilities of institutional review boards as published under 21 CFR part 56.

The inspection revealed that former members of NIRB have kept NIRB documents and they refuse to release any records to the current board. The former NIRB ---------- resignation letter dated ---------- states, "I will retain or store all records and properties of the NIRB presently under my control until directed by a Court of Competent Jurisdiction." The inspection also revealed there are no NIRB standard operating procedures. There is no NIRB document showing current board members, their institutional affiliations, and scientific or non-scientific primary concerns. 21 CFR Part 56 establishes the general standards for the composition, operation, and responsibilities of institutional review boards that review clinical investigations regulated by FDA under sections 505(i) and 520(g) of the FD&C Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA including foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. It is your responsibility to ensure the NIRB complies with all the applicable requirements of the FD&C Act, the PHS Act, and applicable FDA regulations, and to protect the rights, safety, and welfare of subjects, including following written procedures and maintaining IRB records that are accessible for FDA inspection.

You advised the FDA investigator the NIRB has not reviewed any clinical research and NIRB has not approved any clinical research. Please immediately notify this office and the FDA San Francisco District Office listed below upon your initiating review or approval of any clinical research.

Your actions may be verified in future FDA inspections.

FDA has several references available that offer information on human subject protection and the conduct of clinical research. If you have any questions or comments about the contents of this letter or wish to discuss other aspects of bioresearch monitoring, you may contact:

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Sincerely,

/s/

Gilliam B. Conley, Director
Division of Inspections and Surveillance
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cc:

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