



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 11 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Via Federal Express

WARNING LETTER

Cheryl Mortweet, RN
Shepherd Eye Center Institutional Review Board
3575 Pecos McLeod
Las Vegas, Nevada 89121

Dear Ms. Mortweet:

During the period of July 6 through 9, 1999, Mr. Anthony E. Keller, R.Ph., an investigator from the Food and Drug Administration's (FDA) San Francisco District Office, visited the Institutional Review Board (IRB) at Shepherd Eye Center. The purpose of this visit was to determine whether your procedures complied with Title 21, Code of Federal Regulations (21 CFR), Part 50-Protection of Human Subjects and Part 56-Institutional Review Boards. These regulations apply to clinical studies of products regulated by the FDA.

Deviations from 21 CFR Parts 50 and 56 were noted during the inspection. These deviations were listed on form FDA-483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection. Our review of the inspection report revealed the following deficiencies:

- Study coordinators voted to approve studies they were to coordinate. 21 CFR 56.107(e) states that no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- There are no written procedures. According to 21 CFR 56.108(a) and (b), an IRB must follow written procedures. Moreover, 21 CFR 56.115(a)(6) requires the IRB to prepare and maintain documentation of these written procedures.
- There are no minutes covering the initial review and approval of one study or the review of changes for 4 other studies. 21 CFR 56.115(a)(2) requires that minutes of IRB meetings be in sufficient detail to show the actions taken by the IRB during the meeting.
- In 17 out of 19 cases reviewed, minutes of the meeting did not include the attendance or the vote. 21 CFR 56.115(a)(2) requires minutes of IRB meetings to be in sufficient detail to show attendance at the meetings and the vote on action taken, including the number of members voting for, against, and abstaining.

- The rosters of IRB members do not contain the representative capacity of members or their relation to the institution. A list of alternate members is also lacking. According to 21 CFR 56.115(a)(5) an IRB is required to prepare and maintain a list of IRB members identified by name; earned degrees; representative capacity; indications of experience, such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.
- The IRB never established a required frequency of review for clinical studies it reviewed. 21 CFR 56.108(a)(1) and (2) state that an IRB is required to follow written procedures for conducting its initial and continuing review of research and for determining which projects require review more often than annually.

The deviations listed above are not intended to be an all-inclusive list of deficiencies. The IRB is responsible for adhering to each requirement of the law and relevant regulations.

The inspectional report states that in July 1998 Shepherd Eye Center IRB completed transfer to Western IRB (WIRB) of studies under its review and has not reviewed any research since that time. However, it is also stated that the IRB has continued to receive correspondence related to investigational studies, such as the final report for the study [REDACTED] dated January 25, 1999.

Due to the severity of the deviations noted, FDA requires confirmation that Shepherd Eye Center IRB is no longer functioning in the review and approval of investigational studies. Within 15 working days of receipt of this letter, please send this information to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D. This should include the names of all studies previously covered, the date the study was completed and/or closed or the name of the present reviewing IRB and the date review was transferred. Also, please inform us of any and all investigational reports that have been received in your offices since July 1998 and the nature of the disposition of these reports. Failure to respond can result in further regulatory action without additional notice.

Moreover, you may not reinstate review of investigational studies in the future without preparation and adoption of proper operating procedures. Copies of 21 CFR Parts 50 and 56 as well as the FDA Information Sheets are enclosed for your use in such an instance. Also enclosed is a copy of 21 CFR 812.66. This section of the Investigational Device Exemption (IDE) regulations describes an IRB's responsibility for determining whether a device investigational study is significant risk or non-significant risk. These documents will assist you in properly preparing written operating procedures as well as


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an appropriate informed consent document, if you should decide to reconstitute the IRB.

A copy of this letter has been set to FDA's San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502. We request that a copy of your response also be sent to that office.

If you have any questions, feel free to contact Jean Toth-Allen at (301) 594-4723, ext. 141.

Sincerely yours,


for Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological
Health

Enclosures