Inspections, Compliance, Enforcement, and Criminal Investigations

Christus Spohn Hospital Corpus Christi - Memorial Campus

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

WARNING LETTER

VIA UPS EXPRESS May 5, 2011

Ms. Pamela Robertson
Interim President/Chief Executive Officer
Christus Spohn Hospital Corpus Christi – Memorial Campus
2606 Hospital Blvd
Corpus Christi, TX 78405

Dear Ms. Robertson:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection of your Institutional Review Board (IRB) from January 28, 2011, to February 4, 2011, by an investigator from the FDA Dallas District Office. The purpose of this inspection was to determine whether your IRB is in compliance with applicable federal regulations. IRBs that review investigations of devices must comply with applicable provisions of Title 21, Code of Federal Regulations (21 CFR) Part 56-Institutional Review Boards, Part 50-Protection of Human Subjects, and Part 812-Investigational Device Exemptions. This letter also discusses Ms. Estela Chapa's, Vice President/Chief Operating Officer, written response dated February 25, 2011, to the noted violations.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the district office revealed several violations of 21 CFR Part 56-Institutional Review Boards, which are requirements prescribed under section 520(g) (21 USC 360j(g)) of the Federal Food, Drug, and Cosmetic Act (the Act). At the close of the inspection, the FDA investigator presented an inspectional observations Form FDA 483 for your review and discussed the observations listed on the form with Ms. Chapa, Ms. Lamar Gest, Research Coordinator, and Dr. Nester H. Praderio, Medical Staff President/Executive Committee Chairperson, and by teleconference with Ms. Kathy Carson, System Director Accreditation; Dr. Sidney Nau, MD, Risk Management Director; and Jean Dols, PhD, Senior System Director. The deviations noted on the Form FDA 483, your written response, and our subsequent review of the inspection report, are discussed below:

1. Failure to review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. [21 CFR 56.108(c)]

The IRB reviewed FDA-regulated research when less than a majority of the members were present. For example, on June 24, 2009, and August 26, 2009, your IRB failed to meet majority in that only five of **(b)(4)** members were present; however, your IRB's typed meeting minutes indicate your IRB discussed study IRB#**(b)(4)**, "**(b)(4)**."

Your IRB's written response states that the 2006 procedure was officially retired, the committee members implemented and were educated on policy IRB-**(b)(4)** concerning quorum at the February 23, 2011, meeting, and key internal IRB management forms were revised. The response noted also a new policy developed by the Health System Senior Director of Nursing and Research that defines members' responsibilities, entitled "**(b)(4)**," which was approved by the committee on February 23, 2011.

Your IRB's response is inadequate in that it does not sufficiently describe the new policy and how your IRB will document staff training. In your response to this letter, please provide a copy of the new "IRB **(b)(4)**" policy and describe how your IRB will document that appropriate staff have been trained.

2. Failure to prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings, which shall be in sufficient detail to show the vote on IRB actions including the number of members voting for, against, and abstaining. [21 CFR 56.115(a)(2)].

Minutes of IRB meetings are inaccurate and/or incomplete. For example, meetings minutes for **(b)(4)** of your IRB meetings held between February, 2009, and July, 2010, lack pertinent details documenting the number of members voting for, against, and/or abstaining from study approvals.

Your IRB's written response states that committee members were educated on policy IRB-**(b)(4)** concerning meeting minutes, the committee minutes template was revised to include a grid for documenting member votes, the IRB coordinator was educated on the changes in the template, and an internal audit tool has been developed for monthly random review by a non-IRB member.

Your IRB's response is inadequate in that it provided only an excerpt from the meeting minutes template and did not sufficiently describe how your IRB will document staff training. In your response to this letter, please provide a complete copy of the meeting minutes template and describe how your IRB will document that appropriate staff have been trained.

3. Failure to ensure that no IRB member participates in the IRB's initial or continuing review of any project in which the member has a conflicting interest. [21 CFR 56.107(e)]

Your IRB allowed a member with a conflict of interest to participate in study reviews and deliberations. For example, an IRB member was allowed to vote on approval of a study in which he was also a Sub-Investigator. The March 26, 2008, IRB meeting minutes indicate an IRB member, Dr. Choucair, did not abstain from voting on approval of a new study IRB# **(b)(4)**, "**(b)(4)**," of which he was a sub-Investigator.

Your IRB's response states that the 2006 procedure was officially retired, and that the committee approved policies IRB-**(b)(4)** and IRB-**(b)(4)**, members were educated on these policies, the IRB agenda template was revised to include a section for members to declare a conflict of interest (COI), and the committee minutes template was revised to include COI disclosure. Your IRB's response indicates that it will be the responsibility of voting members to disclose any COI in a study submitted to the IRB.

Your IRB's response is inadequate in that it provided only an excerpt from the meeting minutes template and did not sufficiently describe how you will document staff training. In your response to this letter, please provide a complete copy of the meeting minutes template and describe how you will document that appropriate staff have been trained.

The violations described above are not intended to be an all inclusive list of problems that may exist at the IRB. The IRB is responsible for ensuring compliance with the Act and applicable regulations.

Within fifteen working days of receiving this letter, please provide written documentation of the corrective actions noted in you February 25, 2011, letter to FDA's Dallas District Director that you have taken or will take to correct these violations and prevent the recurrence of similar violations.

Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

Your response should reference "CTS # EC100579/E001" and be sent to:

Attention: Anne T. Hawthorn, JD
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
Building 66, Room 3504
Silver Spring, Maryland 20993-0002

A copy of this letter has been sent to Dallas District Office, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm[1].

If you have any questions, please contact Anne T. Hawthorn, 301-796-6561, Anne.Hawthorn@fda.hhs.gov.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Links on this page:

1. http://www.fda.gov/Training/CDRHLearn/ucm162015.htm