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Inspections, Compliance, Enforcement, and Criminal Investigations

Providence Hospital Institutional Review Board, 1/6/10



Department of Health and Human Services

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

WARNING LETTER

VIA FEDERAL EXPRESS

JAN 6 2010

Ms. Bonnie Phipps
Providence Hospital
1150 Varnum Street NE
Washington, D.C. 20017-2180

Dear Ms. Phipps:

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 October 27 through November 3, 2009, by investigators from the FDA Baltimore 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 50 - Protection of Human Subjects, Part 56 -Institutional Review Boards, and Part 812 - Investigational Device Exemptions. This letter also requests prompt corrective action to address the violations cited.

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 serious violations of Title 21, Code of Federal Regulations (21 CFR) Part 56 -Institutional Review Boards. At the close of the inspection, the FDA investigator presented an inspectional observations form FDA 483 for Mr. Spears', President/Chief Executive Officer, review and discussed the observations listed with him, Ms. Tanya Powell, Director of the Quality Management Medical Affairs Department, and Ms. Nikoya Malry, Manager, Clinical Research Center. The deviations noted on the form FDA 483 and our subsequent review of the inspection report are discussed below:

Failure to have adequate written procedures governing the functions and operations of the IRB and to ensure that the IRB reviews proposed research at convened meetings at which a majority of the members are present including at least one member whose primary concerns are in nonscientific areas. [21 CFR 56.108(a), (b) and (c)]

An IRB must prepare, maintain, and follow written procedures that describe the IRB's functions and operations.

The IRB has no written procedures for ensuring that the IRB reviews proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. Examples of these failures include, but are not limited to, the following:

- The IRB has no written procedures for the following:
 - o A procedure for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator the institution.
 - o A procedure for reporting all IRB findings and actions to the investigator and the institution
 - o A procedure for determining which studies require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review.
 - o A procedure for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.
 - o A procedure for ensuring prompt reporting to the Food and Drug Administration of any unanticipated problems involving risks to human subjects or others, and any instance of serious or continuing noncompliance with regulations or the requirements or determinations of the IRB.
 - o The IRB has no written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any instance of serious or continuing noncompliance with the regulations or the requirements or determination of the IRB.
 - o The IRB has no written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any suspension or termination of IRB approval.
- The 2009 IRB roster consists of nine (9) voting members. Minutes for the IRB meeting held on June 10, 2009, identified four (4) members present, in which the IRB reviewed the FDA regulated study entitled, **(b)(4)** without a majority of IRB members present. Please note of the four members present, one individual is considered a non voting member as they are the coordinator of the IRB and one individual counted toward the vote is not listed as an IRB member on the 2009 IRB member roster.
- The 2007 IRB roster consists of nine (9) voting members. Minutes for the IRB meeting held on June 20, 2007, identified five (5) members present in which the IRB reviewed and approved the FDA regulated study entitled **(b)(4)** without a majority of IRB members present. Please note that of the five members present, one individual is considered a non-voting member as they are the coordinator of the IRB and one individual counted towards the vote is not listed as an IRB member on the 2007 IRB member roster.

Failure to include at least one member of the IRB who is not affiliated with the institution and maintain minutes of IRB meetings in sufficient detail. [21 CFR 56.107(d) and 21 CFR 56.115(a)(2)]

IRB membership shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. In addition, an IRB shall prepare and maintain adequate documentation of IRB activities including minutes of IRB meetings shall be in sufficient detail to show attendance, action taken, and the vote of these actions including the number of members voting for, against, and abstaining. Examples of these failures include, but are not limited to the following:

- A review of the curriculum vitae/resumes for each member of the 2009 IRB rosters indicate that all IRB members of the 2009 IRB roster are affiliated with the institution.
- Minutes from the IRB meetings for 2007, 2008, and 2009 do not include the number of members voting for, against, or abstaining from any action on proposed research. Specifically, the June 20, 2007 minutes revealed that the IRB reviewed and approved the FDA regulated study entitled, **(b)(4)**. However, the minutes lack details of the votes on its actions, including the number of members voting for, against, and abstaining.

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 (15) working days of receiving this letter, please provide written documentation of the actions 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. Send your response to: Attention: G. Levering Keely, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 10903 New Hampshire Avenue, W066-3566, Silver Spring, Maryland, 20993-0002.

A copy of this letter has been sent to the Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, MD 21215. 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>*

If you have any questions, please contact Levering Keely at 301-796-5490 or via e-mail at Levering.Keely@fda.hhs.gov.

Sincerely yours,

/s/

*Michael E. Marcarelli, Pharm.D, MS
Director
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health*

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