U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Jamaica Hospital Medical Center IRB 2/24/16

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Silver Spring, MD 20993

WARNING LETTER
FEB 24, 2016

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 16-HFD-45-02-02

Robert I. Mendelson, M.D., FACC, FACP Chairman
Jamaica Hospital Institutional Review Board
Jamaica Hospital Medical Center
8900 Van Wyck Expressway
Jamaica, New York 11418-2832

Dear Dr. Mendelson:

This Warning Letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection of your Institutional Review Board (IRB) that was conducted between August 13 and August 20, 2015, by Ms. Tara K. Carmody, representing FDA. The purpose of this inspection was to determine whether the IRB procedures for the protection of human subjects complied with Title 21 of the Code of Federal Regulations (CFR), parts 50 and 56. These regulations apply to clinical investigations of products regulated by FDA.

This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, and to help ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

At the conclusion of the inspection, Ms. Carmody presented and discussed with you Form FDA 483, Inspectional Observations. We acknowledge receipt of the IRB's September 1, 2015, written response to the Form FDA 483.

From our review of the FDA Establishment Inspection Report, the documents submitted with that report, and your September 1, 2015, written response, we conclude that the IRB did not adhere to the applicable FDA regulations governing the protection of human subjects. We wish to emphasize the following:

The IRB failed to prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings and a list of IRB members [21 CFR 56.115(a)(2) and 21 CFR 56.115(a)(5)].

The IRB is required to prepare and maintain adequate documentation of IRB activities, including:

- Minutes of IRB meetings, which must be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution [21 CFR 56.115(a)(2)]
- 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 [21 CFR 56.115(a)(5)]

The IRB failed to adhere to these requirements. Specifically:

a. For IRB meetings held between January 7, 2013, and July 6, 2015, vote counts were not recorded in the meeting minutes consistently. Instead of recording vote counts, the minutes indicate, for example, "The committee acknowledged and approved the submission." Of the 28 sets of minutes reviewed during the inspection, 9 have no vote counts recorded for any items, and 19 have vote counts recorded for some items only. For example:

1. Minutes of the January 6, 2014, IRB meeting do not include documentation of vote counts for FDA-regulated research that was reviewed and approved.

2. Minutes of the February 3, 2014, IRB meeting do not include documentation of vote counts for FDA-regulated research that was reviewed and approved.

3. Minutes of the January 5, 2015, IRB meeting do not include documentation of vote counts for FDA-regulated research that was reviewed and approved.

4. Minutes of the March 9, 2015, IRB meeting do not include documentation of vote counts for FDA-regulated research that was reviewed and approved.

5. Minutes of the May 4, 2015, IRB meeting do not include documentation of vote counts for FDA-regulated research that was reviewed and approved.

We acknowledge that in your September 1, 2015, written response, you included a copy of the IRB's revised standard operating procedures (SOPs) (version date 14 September 2015). These SOPs and the previous version of the IRB's SOPs both indicate that the votes on actions, including the number of members voting for, against, and abstaining, will be recorded in meeting minutes.

Please submit a written description of the actions the IRB plans to take to ensure compliance with FDA regulations and the IRB's written procedures as they relate to meeting minutes. The response should include a description of any training provided to IRB staff and members and a list of IRB staff and members trained, or a projected timeline of planned training.

Failure to prepare and maintain adequate documentation of IRB meetings raises concerns about the adequacy of the IRB's review process. Furthermore, inadequate documentation raises concerns about whether the IRB members maintained a quorum for the duration of the IRB meetings, and whether any IRB member participated in the review of his or her own research, except to provide information requested by the IRB.

b. During the time period from 2013 to 2015, the IRB failed to prepare and maintain a list of IRB members, in accordance with 21 CFR 56.115(a)(5). Membership lists provided during the inspection indicate that the lists had not been updated as the membership changed, in that members' names listed in meeting minutes and on attendance sheets did not always match the names on membership lists. Specifically:

1. **(b)(6)** is not listed on any membership lists, but she is listed as a voting member in the minutes of 20 meetings held between January 7, 2013, and July 6, 2015.

2. **(b)(6)** is not listed on any membership lists, but he is listed as a voting member in the minutes of 12 meetings held in 2013.

3. **(b)(6)** is not listed on any membership lists, but she is listed as a voting member in the minutes of meetings held on September 9, 2013; October 7, 2013; December 2, 2013; February 3, 2014; March 10, 2014; and September 8, 2014.

4. **(b)(6)** is not listed on any membership lists, but he is listed as a voting member in the minutes of meetings held on June 3, 2013; November 11, 2013; and July 6, 2015.

5. **(b)(6)** is not listed on any membership lists, but he is listed as a voting member in the minutes of a meeting held on December 1, 2014.

We acknowledge your written response indicating that during the inspection, a membership roster template was obtained and a new roster was developed. The roster now includes each member's name, degree, occupation, gender, whether or

not affiliated with the institution, and membership status (member or alternate); and that going forward, membership lists will be updated on a continuous basis and will include a version number and date. If properly carried out, this action appears to be adequate.

Failure to prepare and maintain an accurate list of IRB members raises concerns about the adequacy of the IRB's composition and its ability to safeguard the rights and welfare of research subjects.

This letter is not intended to be an all-inclusive list of deficiencies for the protocols reviewed and approved by the IRB. It is your responsibility to ensure that Jamaica Hospital Medical Center IRB's practices and procedures comply fully with all applicable regulations.

Within fifteen (15) working days of your receipt of this letter, you should notify this office in writing of the actions that will be taken to prevent similar violations in the future. Failure to adequately and promptly address the violations noted above may result in regulatory action without further notice. If you believe you have complied with FDA regulations, include your reasoning and any supporting information for our consideration.

We recommend that you visit the following FDA Web page for information on human subject protections that may assist you in bringing the IRB into compliance with FDA regulations: **http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm (/Drugs/ScienceResearch/default.htm)**.

We appreciate the cooperation shown to the FDA investigator during the inspection. If you have any questions, please contact Constance Cullity, M.D., M.P.H., at 301-796-3397; FAX 301-847- 8748. Your written response and any pertinent documentation should be addressed to:

Constance Cullity, M.D., M.P.H.
Branch Chief
Good Clinical Practice Compliance Oversight Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5354
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely,
{See appended electronic signature page}
David C. Burrow, Pharm.D., J.D.
Acting Director
Office of Scientific Investigations
Office of Compliance

Center for Drug Evaluation and Research
U.S. Food and Drug Administration

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DAVID C BURROW
02/24/2016

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