



[Home](#) > [Inspections, Compliance, Enforcement, and Criminal Investigations](#) > [Enforcement Actions](#) > [Warning Letters](#)

Inspections, Compliance, Enforcement, and Criminal Investigations

Bay Regional Medical Center IRB



Department of Health and Human Services

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

WARNING LETTER

UPS

Ref: 10-HFD-45-09-01

Alice M. Gerard, RN, MSN
President and Chief Executive Officer
Bay Regional Medical Center
1900 Columbus Avenue
Bay City, Michigan 48708

Dear Ms. Gerard:

Between June 2, 2010 and June 4, 2010, Ms. Nancy Bellamy, representing the Food and Drug Administration (FDA), inspected the Institutional Review Board (IRB) at Bay Regional Medical Center (BRMC). 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. We are aware that at the conclusion of the inspection, our investigator(s) presented and discussed with you, a Form FDA 483, Inspectional Observations.

From our review of the establishment inspection report and the documents submitted with that report, we conclude that the IRB did not adhere to the applicable statutory requirements and FDA regulations governing the protection of human subjects. We acknowledge receipt of the written response from Dr. Jay Summer, Vice President Medical Affairs, dated July 20, 2010 to Form FDA 483 but note that this response was received past the fifteen (15) business days from close of the inspection. Thus, while we have reviewed the response, we have not included a discussion of the response in this letter as per the Commissioner's Enforcement Initiative announced August 11, 2009. We wish to emphasize the following:

1. The IRB failed to follow its written procedures for conducting its initial and continuing review of research [21 CFR 56.108(a)(1)].

The IRB is required to follow written procedures in its review and approval of research covered by the regulations. Our inspection revealed that the IRB failed to follow its written procedures in the following situations:

- a) On page 4 of the IRB's Policy and Procedure Manual (under Meetings section) it states "Each study submitted will be assigned to a specific member of the IRB for in-depth review and presentation at the meeting." We note that the BRMC IRB implemented this procedure to document the IRB's review process as a result of the previous FDA

inspection of the BRMC IRB conducted in March 2009. Our current inspection revealed that the IRB failed to follow this procedure at IRB meetings held on July 10, 2009, September 11, 2009, November 13, 2009, January 8, 2010 and March 12, 2010. During this inspection, the IRB secretary confirmed that the IRB has not been following its written procedures to assign the review of protocols to a specific member of the IRB for an in-depth review and presentation at IRB meetings.

b) On page 7 of the IRB's Policy and Procedure Manual (under Records and Reports section) it states "An IRB tracking system will be maintained for continuing review of protocols including the use of expiration date stamps on consent documents to ensure that the federal requirement for IRB review of each protocol is done annually or more frequently as required by the IRB." We note that the plan to develop and maintain a tracking system was added to the IRB's Policy and Procedure Manual as a result of the previous FDA inspection of the BRMC IRB conducted in March 2009. Our current inspection revealed that BRMC IRB has no formal tracking system to monitor the status of protocols under its purview and instead relies on clinical investigators to self-report when continuing review is due. Further, our inspection revealed that the IRB failed to conduct continuing review at appropriate intervals as described in item #2 below. The lack of a properly functioning tracking system and the exclusive reliance on clinical investigators to inform the IRB of upcoming continuing review dates is inadequate and has the potential to result in missed continuing review dates as exemplified in item #2 below.

2. The IRB failed to conduct continuing review of research at intervals of not less than once per year [21 CFR 56.109(f)].

On May 8, 2009, BRMC IRB met and approved the annual renewal for Protocol (b)(4) entitled "(b)(4)." A subsequent continuing review for this protocol was due by May 7, 2010. However, our inspection revealed that continuing review had not been conducted as of the time of the FDA inspection in early June 2010, and that the study was not on the agenda for the upcoming June 4, 2010 IRB meeting.

In addition, with respect to Protocol (b)(4), the IRB did not follow its written procedures for conducting continuing review of research which states on page 6 of the IRB's Policy and Procedure Manual, "Research projects will be reviewed annually. The frequency of reviewing projects, which require review more often than annually, shall be determined individually based on the risk to human subjects involved."

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 BRMC IRB's practices and procedures comply fully with all applicable statutes and regulations.

Within fifteen (15) business days of your receipt of this letter, you should notify this office in writing of the actions you have taken to prevent similar violations in the future. Your written response should include any documentation necessary to show that full and adequate correction will be achieved. Please include the projected completion dates for each action to be accomplished. Failure to adequately and promptly explain the violations noted above may result in regulatory action without further notice. If you believe that Dr. Summer's written response to the Form FDA 483 dated July 20, 2010 fully explains the actions you have taken to prevent similar violations in the future, please communicate that to us in writing within fifteen (15) business days. As noted above, we plan to evaluate your written response to the Form FDA 483 along with any other written material provided as a direct response to this Warning Letter. You may reference the written response dated July 20, 2010 in your response to this letter.

We note, that during the close of the inspection, you informed the FDA Investigator that Bay Regional Medical Center plans to (b)(4) the IRB in the near future. We request you include in your written response to this letter a description of the plan to (b)(4) BRMC IRB, including the plan for the responsible (b)(4) of all studies under the purview of BRMC IRB and the expected timeline for such actions.

We recommend that you visit the following FDA web page for information on human subject protections that may assist you in your efforts to bring the IRB into compliance with FDA regulations:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>^{1□}

We appreciate the cooperation shown to FDA Investigator Bellamy during the inspection. If you have any questions, please contact Kevin Prohaska, D.O., M.P.H., at 301-796-3707; FAX 301-847-8748. Your written response and any pertinent documentation should be addressed to:

Kevin Prohaska, D.O., M.P.H.
Human Subjects Protections Team Lead
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg 51, Room 5356
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely,

/S/

Leslie K. Ball, M.D.

Director

Division of Scientific Investigations

Office of Compliance

Center for Drug Evaluation and Research

Food and Drug Administration

cc: Jay L. Summer, M.D.

Vice President Medical Affairs

Bay Regional Medical Center

1900 Columbus Avenue

Bay City, Michigan 48708

Saad S. Ahmad, M.D.

Institutional Review Board Chairman

Bay Regional Medical Center

1900 Columbus Avenue

Bay City, Michigan 48708

Links on this page:

1. <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>