DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Charles J. Paine
Chief Executive Officer
CHRISTUS Schumpert Health System
One Saint Mary Place
Shreveport, LA 71101

Dear Dr. Paine:

Between April 21 and 25, 2008, Ms. Dana Daigle, representing the Food and Drug Administration (FDA), inspected the Institutional Review Board (IRB) at the CHRISTUS Schumpert Health System. 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 studies of products regulated by FDA. We are aware that at the conclusion of the inspection, our investigator 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, including the revised IRB written procedures provided at the closeout of the inspection, we conclude that the IRB did not adhere to the applicable statutory requirements and FDA regulations governing the protection of human subjects. We wish to emphasize the following:

1. **The IRB failed to require that information given to subjects as part of the informed consent process is in accordance with 21 CFR 50.25 [21 CFR 56.109(b)].**

   When seeking informed consent, the regulations at 21 CFR 50.25 require that each subject be provided with the basic elements of informed consent [21 CFR 50.25(a)], and when appropriate, one or more of the additional elements of informed consent [21 CFR 50.25(b)].

a. For research Project 1125 entitled, "(b) (4) ", our inspection revealed the IRB failed to review and approve an informed consent form that was in compliance with FDA regulatory requirements. We note that the IRB reviewed and approved only three general hospital consent forms for procedures related to Project 1125. None of these consent forms complied with the requirements of 21 CFR Part 50.25.

b. Our inspection revealed the informed consent form approved by the IRB for Project 1121 did not include an explanation of whom the subject should contact for questions about their rights as a research subject, or whom to contact in the event of a research-related injury as required by 21 CFR 50.25(a)(7).

2. The IRB failed to ensure that no member participated in the initial or continuing review of a project in which the member had a conflicting interest, except to provide information requested by the IRB [21 CFR 56.107(e)].

Our inspection revealed five instances in which an IRB member, who was serving as the clinical investigator for a particular research study, voted on the initial or continuing review of that study. The following table lists the dates of the IRB meetings and a brief summary of our findings:

Date of IRB Meeting	Summary of Finding
2/6/2008	Dr. (b) (6) is the clinical investigator for Project 1055. The IRB meeting minutes indicate that he attended the meeting. There was a unanimous vote to approve a consent form change and a unanimous vote to approve the progress report for this study. There is no documentation that Dr. (b) (6) abstained from voting on either action.
2/7/2007	Dr. (b) (6) is the clinical investigator for Projects 1073 and 1074. The IRB meeting minutes indicate that he attended the meeting. There was a unanimous vote to approve the progress reports for these studies. There is no documentation that Dr. (b) (6) abstained from voting on either study.
12/14/2005	Dr. (b) (6) is the clinical investigator for Projects 1091 and 1092. The IRB meeting minutes indicate that he attended the meeting. There was a unanimous vote to approve both of these new proposals. There is no documentation that Dr. (b) (6) abstained from voting on either study.
4/6/2005	Dr. (b) (6) is the clinical investigator for Project 1055. The IRB meeting minutes indicate that he attended the meeting. There was a unanimous vote to approve the progress report for this study. There is no documentation that Dr. (b) (6) abstained from voting on this study.

Date of IRB Meeting	Summary of Finding
2/2/2005	Dr. (b) (6) is the clinical investigator for Projects 1073, 1074, and 1075. The IRB meeting minutes indicate that he attended the meeting. There was a unanimous vote to approve these new proposals. There is no documentation that Dr. (b) (6) abstained from voting on any of these studies.

3. 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 written procedures require that information, including copies of schemas of all proposals on the agenda, be sent to IRB members prior to the meeting. The meeting minutes indicate members were mailed outlines and consent forms for new proposals prior to the meeting, but our inspection revealed that IRB members were not provided copies of protocol schemas for new proposals for the IRB meetings of February 7, 2007 and November 1, 2007. During the inspection, the IRB Coordinator indicated protocol schemas were no longer routinely distributed.

4. The IRB failed to prepare and maintain adequate documentation of written procedures for the IRB as required by 21 CFR 56.108(a) and (b) [21 CFR 56.115(a)(6)].

Specifically, the IRB does not have written procedures for reporting IRB findings and actions to the institution as required by 21 CFR 56.108(a)(1), and does not have written procedures for determining which projects require verification from sources other than the investigator that no material changes have occurred since previous IRB review as required by 21 CFR 56.108(a)(2).

5. The IRB failed to review proposed research at convened meetings at which a majority of the members of the IRB are present [21 CFR 56.108(c)].

The IRB meeting minutes for November 1, 2007, indicate that the membership of the IRB consisted of ten voting members and three *ex-officio* (non-voting) members. Accordingly, a minimum of six voting members were required to be present at the meeting to review proposed research. Our inspection revealed that the IRB reviewed and approved research at the November 1, 2007, IRB meeting with only five voting members present.

6. The IRB failed to conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year [21 CFR 56.109(f)].

Project 1114 was initially approved by the IRB on February 7, 2007. Our inspection revealed there is no documentation in the IRB files that continuing review of Project 1114 was conducted at any time prior to April 25, 2008.

7. **The IRB failed to prepare and maintain adequate minutes of IRB meetings in sufficient detail to show actions taken by the IRB [21 CFR 56.115(a)(2)].**

   Our inspection revealed the minutes for the November 1, 2007, IRB meeting do not list Project 1051 as being reviewed for continuing review. However, the IRB files for Project 1051 contain an IRB re-approval letter and a progress report signed by the IRB Chair as approved at the November 1, 2007 IRB meeting.

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 CHRISTUS Schumpert Health System IRB's practices and procedures comply fully with all applicable statutes and regulations.

The FDA received the IRB's response dated February 23, 2009 to the FDA Form 483 and noted that CHRISTUS Schumpert Health System planned to formally disband the IRB as of April 18, 2009. We request written documentation within thirty (30) working days of receiving this letter of the status of the plan to disband the IRB and transfer any remaining studies to an external IRB. Should CHRISTUS Schumpert Health System decide to re-establish the IRB at any time in the future, it is expected that IRB procedures comply with the protection of human subjects in accordance with Title 21 of the CFR, Parts 50 and 56. These regulations apply to clinical studies investigations of products regulated by FDA.

If you have any questions, please contact me at 301-796-3707; FAX 301-847-8748. Your response and any pertinent documentation should be sent to me at:

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 yours,

{See appended electronic signature page}

Kevin Prohaska, D.O., M.P.H.
Acting Human Subjects Protection Team Lead
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research

cc: Dr. Antonio Pizzaro
IRB Chair
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Ms. Sandee Phagan
IRB Coordinator
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/s/

KEVIN A PROHASKA
07/30/2009