



By Telecopier and
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SEP - 5 2000

Jack Hank, Executive Director
Great Lakes College of Clinical Medicine
1407-B North Wells Street
Chicago, Illinois 60610

Dear Mr. Hank:

This letter is in reply to your letter dated August 11, 2000, to Ms. Patricia Holobaugh of my office, regarding the Great Lakes College of Clinical Medicine (GLCCM) Institutional Review Board. Your letter purports to categorize clinical studies submitted by GLCCM clinical investigators according to whether the studies fall within FDA jurisdiction. Your letter further states, "We understand from our phone conversation [dated August 8, 2000], that this letter will lift the "hold" you have placed on us while we continue to work out the changes you requested in your latest letter..." (emphasis added.)

This letter reiterates to you that the restrictions imposed by FDA on March 9, 2000, remain in effect:

- *No new studies that are subject to 21 CFR Parts 50 and 56 of the FDA regulations are to be approved by your IRB, and*
- *No new subjects are to be admitted to ongoing studies that are subject to 21 CFR Parts 50 and 56 until you have received written notification from this office that adequate corrections have been made.*

Apparently you misinterpreted the telephone conversation between you and Ms. Patricia Holobaugh, CBER representative, held on August 8, 2000. As only one example of incomplete information submitted to FDA, Ms. Holobaugh described that the IRB letter dated May 26, 2000, contained an incomplete table of the IRB's determination of which studies are subject to Parts 50 and 56 of the FDA regulations.

The restrictions remain in effect because the GLCCM letter dated August 11, 2000, does not provide an adequate or complete response to FDA's letters dated March 9, 2000, April 13, 2000, and July 21, 2000.

Furthermore, the GLCCM letter dated August 11, 2000, does not adequately or completely determine which studies are subject to Parts 50 and 56 of the FDA regulations for the following reasons:

1. Neither the IRB nor the clinical investigator have determined whether the studies listed in Section B and D are subject to Parts 50 and 56 of the FDA regulations.
2. The studies listed in Section C are not under an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) at this time. The current enrollment status of these clinical studies is not identified.
3. You did not submit all of the requested information for studies identified as subject to Parts 50 and 56 of the FDA regulations, as requested in FDA's letters dated April 13, 2000, and July 21, 2000.
4. You failed to identify the new IRB reviewing study S084 listed in Section E. We requested this information in our letters dated April 13, 2000, and July 21, 2000.
5. Please provide a detailed explanation and supporting documentation as to why study S068 is listed in Section A. The title indicates that this is a study of a nonsignificant risk device that is under FDA's jurisdiction.

We continue to review your institution's responses in this matter and will determine whether the actions are adequate to permit the IRB to resume unrestricted activities. The restrictions imposed on you IRB will remain in effect until the IRB has demonstrated that it has corrected the extensive violations previously cited and has provided all requested information.

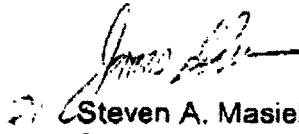
The failure to adequately respond to this letter and to the letter dated July 21, 2000, may result in further administrative actions against your IRB, as authorized by 21 CFR 56.120 and 56.121. These actions include, but are not limited to, the termination of all ongoing studies approved by the IRB and the initiation of regulatory proceedings for disqualification of the GLCCM IRB.

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Your written response should be addressed to:

Ms. Patricia Holobaugh (HFM-664)
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Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448
Telephone: (301) 827-6347

Sincerely,



Steven A. Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation
and Research

cc: James Carter, M.D., IRB Chair
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