GCCM
GREAT LAKES COLLEGE OF CLINICAL MEDICINE, INC.
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February 7, 2001

Ms. Patricia Holobaugh, (HFM-650)
Division of Inspections and Surveillance
Food And Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Dear Ms. Holobaugh:

We are in receipt of your letter of January 2nd. Unfortunately, our IRB's administrator was out of the office because she required surgery, she did return early to assist; however it delayed our response slightly. We are still collecting the information; this is part 1 of our response.

We have followed your instructions and have terminated the listed studies, except for two, one of which has already moved to another IRB and the other was completed in January 2000. The following is the list with the status and enclosures.

M029 Roy Page, M.D. -Adjunct Immune Therapy in the Treatment of Solid Tumors Through Modulation of Signaling Pathways Following Engagement of Humoral and Cell Mediated Responses.
– Has moved to another IRB. This project was terminated from our IRB September 2000.

M026 W.A. Shrader, M.D. – Evaluation of the Effect of the Immunotherapeutic Technique Enzyme Potentiated Desensitization (EPD) for a Considerable Variety of Illness/Conditions/Diagnostic Conditions.
-Has been terminated, enclosed is copy of letter stating Dr. Shrader was informed by Dr. Richman of the FDA that they could continue EPD patients already enrolled in the study.

S055 William Kubitschek, D.O. and Gerlinde Moll – Treatment of Sports Injuries with IBS Inductive Bio-Stumulation Therapy.
– Has been terminated, information that was requested on the need for an IDE was never received.

S060 Alfredo Lopez del Castillo, M.D. – Reconstructive Therapy for Intractable Low Back Pain.
- *Has been terminated, information that was requested on the need for an IND was never received.*

S056 Jack Hinkle, D.O. Chelation Therapy for Removal of Heavy Metals (Specifically Mercury) after DMPS Injection.
-Was not terminated, the project was completed January 2000.

M021 L. Terry Chappell, M.D. – EDTA Chelation & Coronary Artery Disease Patient Registry.
-Terminated, enclosed is a copy of the IND submission and response that an IND was not needed. This project will be revised and submitted to another IRB.

S068 D. Musnick, M.D. and D. Klinghardt, M.D. Low Level Laser for Treatment of Acute and Chronic Muscular – Skeletal Pain and Neurologic Symptoms.
-Has been terminated, we were told by Hugh McClure, FDA Inspector that a letter stating that the investigator called the FDA to ask whether or not an IND/IDE was needed was sufficient as long as the investigator documented the person he/she talked to and the date. We have provided you with this letter, but your response was that it was insufficient information.

We don't understand why you have terminated two of our projects. Project M026 -W.A. Shrader, has been undergoing negotiations with the FDA for several months, and they were told they would be allowed to continue treating existing subjects until this process was completed. Project M021 – L. Terry Chappell, M.D.- recently received a letter from the FDA sating that it did not need an IND to proceed. The latter project was not active anyway. Both of these projects are moving to other IRB's, but there is no reason that we can see that they should have been terminated.

Despite our best efforts to comply with the many additional requirements that you have put upon us in the last year, we have been unable to satisfy you. We have also been unsuccessful in finding a partner to help us. ***Thus we have decided to shut down the GLCCM IRB***. Most of our projects are no longer active, due to the probationary status you have put us under since last spring. We have notified our remaining investigators that we are no longer an IRB and instructed them to inform us whether they will continue under another IRB. We will send this information to you as soon as we receive it.

One of the problems we face is that the restrictions you have placed us under during the past 10 months have eliminated our income. We have no money left in the bank, and our sponsoring organization (GLCCM) also has no money available to fund our operations while we close down. Another problem is that some of our investigators who have terminated their projects have not sent us all the information that you have instructed us to obtain. We will do our very best to comply fully, but it is difficult.

Please send us instructions in the correct procedure to shut down an IRB. We could find nothing in the FDA information sheets.

The information comes from me but was provided to me by the GLCCM IRB officials, because you have refused to communicate with them directly.

Thank you,

Barbara Grunewald
Executive Director GLCCM