MINUTES
INSTITUTIONAL REVIEW BOARD
GREAT LAKES COLLEGE OF CLINICAL MEDICINE
MAY 5, 2000
ACAM MEETING IN DALLAS

PRESENT: 12 members present of 16 membership. Paula Bickle, Effie Mae Buckley, Tammy Born, Terry Chappell, James Carter, George Kindness, Frances Greenway, Garry Gordon, Tim Guilford, Conrad Maulfair, Ted Rozema, Bob Smith. Guests: Betsey Angus, Jay Nielsen, Susan Levin, and Colleen Maulfair. Note: Paula Bickle left early.

CALL TO ORDER AND APPROVAL OF MINUTES: The meeting was called to order by Dr. Terry Chappell at Dr. Carter's request. The Minutes were reviewed. A motion to approve the minutes was made by Tammy Born and seconded by Garry Gordon. The vote was 12-0 in favor.

PROJECTS FOR REVIEW: There were no new projects for review due to the FDA's restriction of new studies.

REVIEW OF THE SECOND FDA LETTER: Dr. Chappell reviewed the FDA letter that was distributed in the members packets prior to the meeting.

DISTRIBUTION OF THE BELMONT REPORT: The Belmont Report was distributed in the members packets to be read prior to the meeting. All members stated that they had read the report.

REVISION OF THE POLICY AND GUIDELINES: The revised Policy and Guidelines were distributed in the members packets prior to the meeting. In reviewing the revisions, the motion to approve the revised Policy and Guidelines was made by Tim Guilford and seconded by Garry Gordon, the vote was 12-0 in favor.

REVISION OF THE INFORMED CONSENT: The revised consent form guidelines were distributed prior to the meeting. The motion to approve the revised consent form guidelines was made by Gary Gordon, and seconded by Tim Guilford. The vote was 11-0 in favor.

REVIEW OF ALL ACTIVE PROJECTS RE: investigational new drug or investigational new device exemption: All projects were reviewed in their entirety by Dr Chappell and discussed with all members for whether the need of an IND or IDE was needed for projects that were activated prior to information of whether or not an IND/IDE was needed (sic). Several were felt that an IND/IDE might be required (sic). The board directed that Ms. Angus send a letter requiring that these investigators to inquire about the need for an IND/IDE to the FDA before the studies could resume, after the suspension by the FDA is lifted (sic).

TERMINATION NOTICES: The following studies were terminated. Dr. Heimlich's study S043 Induced Malaria Therapy was terminated by the FDA request in the letter to the IRB of April 13th. Dr. Mauer's study S004 Phototherapy as a Modality, Dr. Porters S049 Chelation Therapy and Paula Bickle's study S081 A Protocol for Studying DMPS, were terminated by the IRB due to lack of response to the annual continuing review.

CONTINUING REVIEWS/UPDATES: The board felt that no continuing reviews should be approved at this time. It was agreed that all the studies would need to have the IND/IDE information and revised consent forms submitted before the continuing reviews are considered. All investigators will be contacted.

ADVERTISEMENTS: The board felt that no advertisements should be approved at this time. It was agreed that all the studies would need to have the IND/IDE information and revised consent forms submitted before the advertisements would be considered. All investigators will be contacted.

REVIEW OF CONSENT FORMS: Each Board member reviewed several of the previously approved consent forms based on the new consent form checklist. All were found to be deficient with the exception of one. All investigators will be requested to revise their consent forms and resubmit them for IRB approval prior to reactivation.

MEMBERSHIP: The FDA informed the IRB in the April 13th letter that Effie Buckley and Russell Jaffe were not considered to be non-affiliated members. Dr. Carter presented the Board with the curriculum vitae of Carol Weideman PhD as a new member. The Board reviewed and discussed Carol Weideman as the non-affiliated member. The motion to approve Carol Weideman as a new non-affiliated member was made by Gary Gordon, and seconded by Tim Guilford. The vote was 11-0 in favor.

OLD BUSINESS: There was no old business.

NEW BUSINESS: Dr. Gordon moved that the IRB invite the FDA inspector to attend our next meeting in Pittsburgh and future meetings as well. This was seconded by Dr. Kindness and approved by an 11-0 vote.

The request to have an application fee was presented by Betsey Angus. The motion to approve the new application fee of $ 200.00 was made by Gary Gordon and seconded by Effie Buckley. The vote was 11-0

Adjournment: The motion to adjourn was made by Tammy Born and seconded by Gary Gordon. The vote was 11-0 in favor. The next scheduled meeting will be September 16th in Pittsburgh, Pennsylvania.

Respectfully Submitted,

L. Terry Chappell, M.D.
LTC/bta