MINUTES
INSTITUTIONAL REVIEW BOARD
GREAT LAKES COLLEGE OF CLINICAL MEDICINE
ATLANTA, GA
FEBRUARY 25, 2000 Friday 4:30 p.m.

Present: 11 members of 16 membership were present. Effie Mae Buckley, Tammy Born, Jim Carter, Terry Chappell, Frances Greenway, Tim Guilford, Russell Jaffe, George Kindness, Ted Rozema, Bob Smith and John Trowbridge. Guests: Betsey Angus, Jack Slingluff, William Westendorf, Patrica Bender, William Mitchell, William Sunderwirth, Richard Walker, Ralph Cooper, Richard Keller, Lawrence Young, Gary Moore, William Watson. Note to attendance- Frances Greenway arrived late.

Call to Order: The meeting was called to order by Dr. Terry Chappell at Dr. Carter's request. A motion to approve the Minutes was made by Russ Jaffe, and seconded by Effie Buckley. The vote was 10-0 in favor.

Project for review: ***Primary reviewers: Drs. Carter, and Born***

Warren Levin, M.D., with Richard Walker, Ph.D. presenting: S084 Effects of Growth Hormone (GH) or Growth Hormone Releasing Factor (GRF) on Age-Related Insulin Resistance, Pulmonary Function and Quality of Life.

Dr. Carter presented the study as a well-written study. The FDA has exempted an IND by letter. After Dr. Walker answered questions. The IRB wanted clarification on termination, how many patients will be enrolled. Dr. Carter and Dr. Born would like to see more screening for cancer with tumor markers. There was some concern that there might be difficulty in attaining statistical significance. Multi-variant analysis might be required. The SF 36 was suggested as a possible added outcome measure. The motion was made by Tammy Born and 2nd by Jim Carter to approve this study as a non-significant risk with approval expiring on October 27, 2001 the closest meeting, not exceeding one year. The vote was 10-0 in favor. Tim Guilford abstaining.

Projects for re-review and multi-center:

Garry Moore: request for a multi-center project: S077 Ca-EAP Therapy as an Adjunct in the Therapy of Patients with Multiple Sclerosis.

After discussion of the project the motion was made to table the study until the inclusion of how many sites are proposed, how they would interact, where they would be located, how many patients may be involved, and the need for an IND. The IRB had heard of a patient of Dr. Robert Atkins that had suffered an MI close to treatment with CaEAP. Dr. Moore was asked to check this out an report to the IRB. The motion was by John Trowbridge and 2nd by Ted Rozema. The vote was 11-0 in favor.

Bill Westendorf: request for a multi-center project: M010*Amalgam Removal and Mercury Detox.* (rewritten, 1992 approval)

After discussion with Dr. Westendorf, the motion to table this project was made by Ted Rozema and 2nd by Tammy Born until the inclusion of IND information and an estimated number of patients are included. Also the endpoints of the study need to be uniform and the suggestion was made to divide the study into groups. The vote was 10-0 in favor. Note: Dr. Trowbridge was not present.

Steven Arye: reactivate project: M022 *Insulin Potentiation Therapy (IPT) in the Management of Malignant Neoplastic Diseases.*

This study was approved 9/20/97 and was placed on hold for over one year. The motion to re-activate approval at moderate risk with approval until September 16, 2000, was made by

George Kindness and 2nd Effie Buckley, subject to contacting the FDA on the possible need for an IND. It was suggested that the title include " Adjuvant". The vote was 11-0 in favor.

Continuing Review/ updates:

Dr. Pomeroy's study M061 Pain Alleviation and Joint Function. This project involves the use of spinal length needles in areas away from the spinal cord. There are 1,500 patients enrolled. The motion to approve the continuing review of Dr. Pomeroy's study M061 Pain Alleviation and Joint Function was given at *significant risk* with the approval until September 16, 2000 by John Trowbridge and 2nd by Bob Smith. The vote was 11-0 in favor.

Dr. Heimlich's study S043 Induced Malaria Therapy... The treated HIV patients in this study are still doing well. The exception of not including the Patient Bill of Rights due to complications of the data being collected in China, and a request to submit data to the IRB, the motion to approve Dr. Heimlich's study S043 Induced Malaria Therapy... was given at *significant risk* with the approval until September 16, 2000 by John Trowbridge and 2nd by Tim Guilford. The vote was 11-0 in favor.

Dr. Heimlich's study S074 Heimlich Maneuver for Asthma. No subjects have been enrolled at this time. The motion to approve Dr. Heimlich's study S074 Heimlich Maneuver for Asthma was given at *minimal risk* with approval for 8 months expiring on October 27, 2000 the closest meeting, not exceeding one year, by John Trowbridge and 2nd by Tammy Born. The vote was 11-0 in favor.

Dr. Young's study S076 A Gentle Physical Exercise...There have not been any subjects enrolled. There has not been any advertising. The motion to approve Dr. Young's study S076 A Gentle Physical Exercise...was given at *minimal risk* with approval for 8 months expiring on October 27, 2000 the closest meeting, not exceeding one year. The vote was 11-0 in favor.

Dr. Musnick and Klinghardt's study S068 Low Level Laser for Treatment of Acute...The results are good and there have been no complications. This device qualifies for minimal risk under FDA guidelines. The motion to approve Dr. Musnick and Klinghardt's study S068 Low Level Laser for Treatment of Acute...was given at *minimal risk* with approval for 8 months expiring on October 27, 2000 the closest meeting, not exceeding one year, by Ted Rozema and 2nd by Effie Buckley. The vote was 11-0 in favor.

Dr. Lopez del Castillo study S048 Reconstructive Therapy for Intractable Low Back Pain...This study is similar to Dr. Pomeroy's study. The motion to approve Dr. Lopez del Castillo study S048 Reconstructive Therapy for Intractable Low Back Pain...was given at significant risk with approval for 6 months expiring on September 16, 2000 by John Trowbridge and 2nd by Frances Greenway. The vote was 11-0 in favor.

Dr. Shrader's study M026 Evaluation of EPD... There are very complete data for this study and the procedure appears much safer that conventional allergy desensitization. The motion to approve Dr. Shrader's study M026 Evaluation of EPD... was given at *significant risk* with approval for 6 months expiring on September 16, 2000 by John Trowbridge and 2nd by Effie Buckley. The vote was 10-0 in favor. Dr. Chappell abstaining because he is an investigator.

Termination: The IRB accepted the termination/completion of the projects by Lester Adler, Stephen Edelson, Ted Rozema, Dr. Royal/BioRem.

FDA inspection .Dr. Chappell reviewed the FDA inspection of the IRB files on 11/16 -12/1/99 and 1/6/00. Dr. Chappell also reviewed the rewritten Policy. It was rewritten to better reflect how the IRB operates. There are a few things yet to be added.

Chairman designate members: Dr. Carter designated the following IRB members to get expedited review ~~o~~-investigators requesting to join multi-centered projects. M026 – Dr. Shrader's project, by Effie Buckley. M021-Dr. Chappell, by Bob Smith. M013 – Paula Bickle, by Francis Greenway. M023-Dr. Pomeroy, by Barbara Faber. The CV's will be reviewed, and upon compliance of the multi-center rules, the designated members will approve co-investigators.

Review of Policy: Upon reviewing the Policy, the motion to table was made by John Trowbridge to review and discuss the Policy again at the next meeting and 2nd by George Kindness. The vote was 10-0 in favor.

Review of the Guidelines, which are sent out to individuals wishing to present a project to the IRB. The motion to table the discussion until the next meeting was made by Tim Guilford and 2nd by Bob Smith. The vote was 10-0 in favor.

Shrader's Canadian Data: Dr. Chappell informed the Board that Dr. Shrader has been including the Canadians data in the data he submits to the IRB. Dr. Shrader does not require the Canadians to be in compliance of the IRB rules. It was requested that Dr. Shrader be sent a letter to not include the Canadian data under the IRB supervision.

Review of Patient Bill of Rights: It was noted that several things were duplicated in the Patient Bill of Rights and the guidelines for the consent form. It was also brought up to include patient costs and insurance coverage. These documents will be revised and presented at the next meeting.

Dr. Wempen's letter: This was reviewed and discussed. For clarification of "IRB protection" there is now ~~i~~ement in the IRB guidelines stating that the IRB does not <u>protect</u> investigators, but it supervises and ~~ov~~sees approved activities of research studies.

Old Business: there was no old business.

New Business: Dr. Chappell discussed a letter in JAMA regarding IRB certification program from the National Institutes of Health (NIH) Office for Protection for Research Risks (OPRR) group called Applied Research Ethics National Association (ARENA). ARENA is starting a certification program for IRB members and staff. Dr. Jaffe suggested that Betsey Angus attend. Dr. Chappell would like anyone else that would be interested to attend also.

Adjournment: The motion to adjourn was made by Ted Rozema and seconded by Tim Guilford. The vote was 11-0 in favor. The next scheduled meeting will be May 5th during the ACAM meeting in Dallas.

Respectfully Submitted,

Terry Chappell, M.D.
Secretary