MINUTES
INSTITUTIONAL REVIEW BOARD
GREAT LAKES COLLEGE OF CLINICAL MEDICINE
MARCH 15, 1990
ASHEVILLE, NC


CALL TO ORDER AND APPROVAL OF MINUTES: The meeting was called to order by Dr. Terry Chappell. The minutes were reviewed. Dr. Bickle noted that she has 3 projects active for April. Also, she stated she was researching the monitoring of sites. A motion was made by Dr. Geurink-Born and seconded by Dr. Bickle to approve the minutes. The vote was 9-0 in favor.

PROJECTS FOR REVIEW: Preliminary review of Dr. Hauser's project-investigative Treatment Protocol Employing Intravenous Human Secretin in the Treatment of Autism. Preliminary review by Effie Mae Buckley, Russell Jaffe, and Conrad Maurer. Diane Neuziel was present to discuss the project for Dr. Hauser. Dr. Bickle stated that it would need an IND. Questions reviewed were if synthetic secretin has approval for use, if it was to be a multi-centered. LIL's need to be checked for bacteria. Injections would be used instead of routine 4 injections. The cost should be stated. More specific numbers should be included in the consent form. More endpoints and requested the protocol that they were using. Ms. Neuziel contacted Dr. Hauser regarding the question. He stated to her that he was aware they would need an IND. LIL's were not used by Hertz the lab he uses. There was no set protocol for the multi-center mentioned in his study. He also stated to her that Great Smokies was not included because he didn't want too many variables. Dr. Carter made the suggestion that the IRB bring together Dr. Hauser with Dr. Katsama who already had an approved project in research. After discussion the motion to table the project was made by Ted Rozema and seconded by William Faler.

Dr. Chappell informed the Board of the expedited approval of the project by Paula Bickle and Carol Simontacchi. Study to Evaluate if Consuming a Nutrient-Dense Breakfast Drink Affects Cognitive Abilities and Mood States.

Dr. Chappell informed the Board that he was making revisions to the Registry and would have it ready to present at the next meeting.

APPROVAL OF ADDITIONS: The following names were approved to be added to the Investigator:

- Paula Bickle's DMPS project- Stephen Kennedy, M.D. and Douglas Matz, M.D. It was moved by Dr. Geurink-Born and seconded by Dr. Rozema that they be approved. The vote was 9-0 in favor of approval. Dr. Bickle seconding.

- Kent Pomeroi's Pain Alleviation project-Jay Nielsen, M.D. It was moved by Dr. Geurink-Born and seconded by Dr. Rozema that they be approved. The vote was 11-0 in favor.

- Royal's AM-2 project- Mack Bonner, M.D. and Connie Ross, M.D. It was moved by Dr. Rozema and seconded by Dr. Geurink-Born that they be approved. The vote was 11-0 in favor.

- Bickle presented her review of the IRB fees. She contacted several IRBs to ask what the fees were. She stated ours were low. She suggested that the submission fee be doubled. Multi-center co-investigators fee should be $150.00 instead of $75.00. Dr. Chappell asked to table the discussion.

- Chappell informed the Board the policy on advertising was sent to all investigators and would be included with the packets. Attendance of investigators was discussed. Dr. Chappell informed the Board of the tally of all investigators, everyone to recommend to the GLCCM Board that the EPD Society meet in conjunction with GLCCM was made by Ted Rozema and seconded by George Kinness. The vote was 11-0.