

MINUTES
INSTITUTIONAL REVIEW BOARD
GREAT LAKES COLLEGE OF CLINICAL MEDICINE
MARCH 13, 1999
ASHEVILLE, NC

PRESENT: 11 members present of 10 membership. Terry Chappell, James Carter, George Kindness, William Faber, Barbara Faber, Frances Greenway, Tammy Geurkink-Born, Russell Jaffe, Ted Rozema, Bob Smith. Guests: Diane Neuzil, Mack Bonner, Charles Adams, Beth Kanihil, Dennis Courtney, Roy Page, Jean Berry, Arthur Weissen, LuAnne Young, Vicki Sims, and Yveta Germano.

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 not 4. Also, she stated she was to research the monitoring of sites. A motion was made by Dr. Geurkink-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 Mautfair. Diane Neuzil was present to 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-center, LIL's need to be checked for bacteria, 2 injections would be used instead of routinely 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. Neuzil 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. Kotsanis who already had an approved project in secretin. After discussion the motion to table the project was made by Ted Rozema and seconded by William Faber.

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 Chief Investigators. Paula Bickle's DMPS project- Stephen Kennedy, M.D. and Douglas Matz, D.M.D. It was moved by Dr. Geurkink-Born and seconded by Dr. Rozema that they be approved. The vote was 10-0 in favor of approval. Dr. Bickle abstained.

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

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

r. Bickle presented her review of the IRB fees. She contacted several IRB's to ask what the fees were. She stated ours are low. She suggested that the submittal fee be doubled and multi-center co-investigators fee should be \$150.00 instead of \$75.00. Dr. Chappell asked to table the discussion.

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