

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

6751 Steger Drive  
Cincinnati, OH 45237-3097  
(513) 679-2700

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED		PERIOD OF INSPECTION	C.F. NUMBER
To: I. Terry Chappell, M.D.		11/16-12/1/99	1529279
TITLE OF INDIVIDUAL		TYPE ESTABLISHMENT INSPECTED	
IRB Secretary		Institutional Review Board	
FIRM NAME		NAME OF FIRM, BRANCH OR UNIT INSPECTED	
Great Lakes College of Clinical Medicine IRB		same	
STREET ADDRESS		STREET ADDRESS OF PREMISES INSPECTED	
122 Thurman Street		same	
CITY AND STATE (Zip Code)		CITY AND STATE (Zip Code)	
Bluffton, OH 45817		same	

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

1. The document entitled "Basic Policy for Protection of Human Research Subjects for The Great Lakes College of Clinical Medicine is not a relevant and functional document in that it does not accurately and completely describe the actual policies and procedures employed by the IRB in its review and approval/disapproval of proposed and ongoing clinical research involving human subjects. The document is, in large part, no more than a compilation of direct quotes taken from Title 21, Part 50 & 56 of the Code of Federal Regulations that contains the general requirements for the composition, operation and responsibility of Institutional Review Boards and the general requirements for Informed Consent of Human Subjects.

*Correction for the observation promised by 6/1/00.*

2. IRB members who have a conflicting interest in proposed research submitted to the IRB for review and approval are not always excluded from participation in the deliberation and voting on the subject research. In at least two instances, an IRB member having a conflicting interest in proposed research was allowed to take part in the deliberation and voting on the research. For example, Dr. George Kindness, an IRB member, was actively involved in deliberation and voting on the research projects entitled "Stimulated Autologous Immune Serum and Autologous Tumor Vaccine in the treatment of Refractory Solid Tumors" (GAT) and "Multi-Centered Project #M019: Investigational Proposal for the Study of AM-2". In the case of GAT study, Dr. Kindness' laboratory (AmScor Medical Laboratories, Inc.) manufactured the tumor vaccines used in the study and in the case of the AM-2 study, Dr. Kindness' laboratory served as the testing laboratory for the study until 6/98. Dr. Kindness should have been excluded from deliberation and voting on these studies, however, he made the motion to approve both studies and was including in the voting.

*Observation corrected but not verified.*

3. Continuing review of approved research is not always conducted at convened meetings of the IRB. In most cases, updates/progress reports submitted by clinical investigators are not discussed at the IRB meetings. Copies of the updates/progress reports are distributed to the IRB members prior to the meetings, however, in most cases no discussion and voting takes place and no action (ie. reapproval/termination) is taken. Likewise, the clinical investigators are not notified of actions taken by the IRB, if any, as a result of the submitted progress reports.

*Correction for the observation promised by 6/1/00.*

4. The provision for expedited review of proposed research is not always appropriately applied by the IRB. For example, on 12/22/97 a research project designed to evaluate the clinical relevance of heavy metal removal by Calcium Disodium Ethylene Diamine Tetra Acetic Acid in pediatric patients with ADD was approved using expedited review procedures.

*Observation corrected but not verified.*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Hugh M. McClure III</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Hugh M. McClure III, Investigator	DATE ISSUED 11-30-99 <i>12/1/99</i>
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TITLE OF INDIVIDUAL IRB Secretary		TYPE ESTABLISHMENT INSPECTED Institutional Review Board	
FIRM NAME Great Lakes College of Clinical Medicine IRB		NAME OF FIRM, BRANCH OR UNIT INSPECTED same	
STREET ADDRESS 122 Thurman Street		STREET ADDRESS OF PREMISES INSPECTED same	
CITY AND STATE (Zip Code) Bluffton, OH 45817		CITY AND STATE (Zip Code) same	

5. Review and approval of proposed research at convened meetings of the IRB is not always performed with a majority of the members present. For example, at the IRB meeting held on 5/1/98 only six (6) of the 16 members were eligible to vote due to three (3) members being excluded for conflict of interest. Although the quorum requirements were met at the beginning of the meeting with nine (9) of the 16 members present and eligible to vote, the quorum failed with the exclusion of the three (3) previously eligible members. Deliberation and voting was performed for the Multi-Center Clinical Registry on EDTA Chelation Therapy and Cardiovascular Disease. The research received unanimous approval by the (6) members present. Likewise, at the IRB meeting held on 5/7/99, a majority of the members (10 of 16) were present at the beginning of the meeting. Two members were excluded due to conflict of interest and left the room for discussion and voting on revisions to the EDTA Registry. As a result, the number of eligible members was reduced to eight (8) causing the quorum to fail. Nevertheless, deliberation and voting on the revisions proceeded. The revisions received unanimous approval from the eight remaining members. At the IRB meeting held on 11/20/98 only eight (8) of the 16 members were present. Although a majority of the members were not present at this meeting, research projects were reviewed and approved.

*Observation corrected but not verified.*

6. Research projects not qualifying for expedited review are not always reviewed and approved at convened meetings of the IRB. In the case of the projects entitled "Effects of Intravenous Secretin Infusion in Autistic and Learning Compromised Individuals" and "Evaluation of the Effect of Immunotherapeutic Technique Enzyme Potentiated Human Desensitization (EDP) for a Considerable Variety of Illness Conditions/Diagnostic Conditions" study materials were forwarded to the members and voting was accomplished by each member faxing their vote to the IRB office. Both projects were approved.

*Corrected but not verified.*

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