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| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION | | DISTRICT ADDRESS AND PHONE NUMBER 1141 Central parkway Cincinnati, OH 45202 513-684-3501 | |
| NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: L. Terry Chappell, MD | | PERIOD OF INSPECTION 10/7&12/21/94 | C. F. NUMBER |
| TITLE OF INDIVIDUAL Secretary | | TYPE ESTABLISHMENT INSPECTED IRB | |
| FIRM NAME Great Lakes Assoc. of Clinical Medicine- | | NAME OF FIRM, BRANCH OR UNIT INSPECTED IRB 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 | |
| DURING AN INSPECTION OF YOUR FIRM (I) (X) (Z) OBSERVED: | | | |
| <p>1. The original protocol (9/4/93) for "[REDACTED]" was approved at the 9/18/93 meeting pending suggestions for revisions. The main suggestion was having the entry criteria more clearly defined.</p> <p>A revised protocol was submitted on 11/24/93. In that protocol the maximum daily dose was defined to be [REDACTED] cc. The initial protocol was [REDACTED] cc daily. There is no indication the IRB approved this change. The frequency of progress reports was not listed in the 10/13/93 letter to the Investigator or in the minutes of the September 18, 1993 meeting.</p> <p>A 9/13/94 letter from the Investigator states the FDA put the study on hold on 1/5/94, and as of July 1994, the study was still on hold. There is no indication whether subjects had ever been enrolled in the study.</p> <p>2. There is no progress report available for "[REDACTED]" which was originally approved on 5/15/93.</p> <p>3. Numerical counts of the voting is not recorded in the minutes.</p> <p>4. THE NON-SCIENTIFIC MEMBERS OF THE COMMITTEE WAS NOT PRESENT AT THE 11/5/94 MEETING.</p> | | | |
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE <i>Gilbert J. Heidenblut</i> | EMPLOYEE(S) NAME AND TITLE (Print or Type) Gilbert J. Heidenblut, INV. | DATE ISSUED 12/21/94 |