DEPARTMENT OF HEALTH & HUMAN SERVICES

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June 1, 2001

Robert G. Brooks, M.D.
Secretary
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399-1701

Judge Kathleen A. Kearney
Secretary
Florida Department of Children and Families
1317 Winewood Boulevard
Building 1, Room 202
Tallahassee, Florida 32399-0700

RE: Human Subject Research Protections Under Multiple Project Assurance (MPA) M-1350

Dear Dr. Brooks and Judge Kearney:

The Office for Human Research Protections (OHRP) has reviewed Dr. Brooks' May 8, 2001 report which was submitted in response to OHRP's February 16, 2001 letter.

OHRP finds that the following corrective actions taken by the Florida Department of Health/Florida Department of Children and Families (FDH/FDCF) adequately addresses the findings and required actions stipulated by OHRP in its February 16, 2001 letter:

(1) FDH/FDCF has audited all Federally sponsored research and ensured that each protocol has had appropriate continuing review by the FDH/FDCF Institutional Review Board (IRB).

(2) FDH/FDCF has developed adequate written IRB policies and procedures.

(3) FDH/FDCF have expanded the minutes of IRB meetings to include a description of the discussion taking place at the meetings and a recording of the votes on each agenda item.

(4) FDH/FDCF has hired a new IRB chair and Director of research to address issues related to protection of human subjects.

(5) Increased funding has been budgeted for IRB staff and training of IRB members on Federal regulations related to protection of human subjects.

(6) New databases have been created to assist the IRB staff with tracking of protocols to address issues related to continuing review of projects.

(7) The FDH/FDCF IRB has added individuals to the IRB with the proper expertise to review research involving children and prisoners.

As a result of the above determination, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

At this time OHRP has the following additional guidance:

(1) The FDH/FDCF IRB policies and procedures (Page 9, Item V. C. 2.) indicate that reports of injury and/or unanticipated problems will be submitted to the Office for Protection from Research Risks (please change to OHRP). HHS regulations at 45 CFR 46.103(b)(5) require that any unanticipated problems involving risks to subjects or others must be promptly reported to the IRB, appropriate institutional officials, Federal Department or Agency head, and OHRP. Please note that:

(a) Only those injuries determined to be unanticipated problems involving risks to subjects or others must be reported in accordance with HHS regulations at 45 CFR 46.103(b)(5).

(b) In addition to OHRP, such reports should be forwarded to the funding agency, where appropriate.

(c) OHRP acknowledges that the Food and Drug Administration (FDA) regulations also impose additional reporting requirements for FDA regulated research.

(2) OHRP notes that the minutes of the FDH/FDCF IRB meetings indicated that a number of individuals attend via teleconference. OHRP guidance which may be found at http://ohrp.osophs.dhhs.gov/g-topics.htm permits the use of teleconference for IRB meetings provided that all IRB members receive appropriate protocol materials in advance of the meeting.

OHRP appreciates the commitment of your institution to the protection of human subjects of research. Please contact me if you have any questions regarding this matter.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: John O. Agwuobi, M.D., Chairperson, IRB, FDH/FDCF
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