DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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August 31, 2004

John Agwunobi, M.D., M.B.A.
Secretary of Health
Florida Department of Health
4052 Bald Cypress Way, Bin A-07
Tallahassee, Florida 32399-1708

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 4682

Dear Dr. Agwunobi:

As you know, the Office for Human Research Protections (OHRP) conducted an on-site evaluation of human subject protections at the Florida Department of Health (FDOH) on August 17-19, 2004. The evaluation, conducted by two OHRP staff with the assistance of two consultants, included meetings with institutional officials, six Institutional Review Board (IRB) members, IRB administrative staff, and investigators supported by the Department of Health and Human Services (HHS). The evaluation involved review of IRB files of over 16 protocols and the minutes of more than six IRB meetings.

In the course of the OHRP review, the IRB chair, IRB members, and IRB administrative staff displayed an enthusiastic and sincere concern for and commitment to the protection of human subjects, and stated that they view themselves as providing a valuable service to subjects and the research community. The staff of the IRB office were helpful and accommodating to OHRP during the site visit.

Findings:

(1) The first footnote following HHS regulations at 45 CFR 46.101(i) states that the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners (Subpart C). OHRP finds that Protocol #1070, "Evaluation of HIV/AIDS Case Reporting of Prisoners in Florida," was inappropriately determined to be exempt, in contravention of Footnote 1 following 45 CFR 46.101(i).

(2) HHS regulations at 45 CFR 46.116(d) require that the IRB find and document four specific criteria when approving waiver or alteration of some or all of the required elements of informed consent. OHRP finds that the IRB failed to document the four required criteria for waiver of informed consent when reviewing studies #1351 and #1366.

(3) HHS regulations at 45 CFR 46.305-306 require specific findings on the part of the IRB for approval of research involving prisoners. OHRP's discussions with IRB members and its review of IRB documents reveal no evidence that the IRB makes the required findings when reviewing such research.

(4) HHS regulations at 45 CFR 46.404-407 require specific findings on the part of the IRB for approval of research involving children. OHRP's discussions with IRB members and its review of IRB documents reveal little evidence that the IRB makes the required findings when reviewing research involving children.

(5) OHRP finds that the institution does not have written IRB procedures for ensuring prompt reporting to appropriate institutional officials, any Department or Agency head, and OHRP of any unanticipated problems involving risks to subjects or others, as required by HHS regulations at 45 CFR 46.103(a) and (b)(5).

Additional Questions and Concerns:

(6) [Redacted]

(7) [Redacted]

Required Actions:

By September 10, 2004, please provide OHRP with a satisfactory corrective action plan to address the above determinations, and respond to the above concerns. OHRP is available to assist FDOH in the development and implementation of the corrective action plan.

At this time, OHRP offers the following additional guidance:

(8) Where HHS regulations require specific findings on the part of the IRB, such as (a) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)]; (b) approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207); (c) approving research involving prisoners (see 45 CFR 46.305-306); or (d) approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings. OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

OHRP appreciates your institution's commitment to the protection of human subjects. Please do not hesitate to call me if you have any questions.

Sincerely,

Karena Cooper, J.D., M.S.W.
Compliance Oversight Coordinator
Division of Compliance Oversight, OHRP

cc: Ms. Nancy Humbert, FDOH
Dr. Susan Philips, FDOH
Dr. Paul Arons, IRB Chair, FDOH
Lynn H. Riley, CPA, FDOH
Dr. Bernard Schwetz, OHRP
Dr. Melody Lin, OHRP
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