DEPARTMENT OF HEALTH & HUMAN SERVICES

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Mr. Ira Clark
President
Public Health Trust
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Mr. Gus Godoy
Research Administrator
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RE: Human Research Subject Protections Under the Multiple Project Assurance (MPA) M-1196

Research Projects: Research Projects Involving Prisoners

Dear Dr. Altman and Messrs. Clark and Godoy:

The Office for Human Research Protections (OHRP) has reviewed your letters of August 23, 2000 and of September 8, 2000 with its appendices.

Based on its review, OHRP finds that the University of Miami (UM) has taken the following required actions stipulated by OHRP in its July 31, 2000 letter.

(1) The UM has modified its procedures so that the prisoner representatives serve as full voting members whenever the Institutional Review Boards (IRBs) review research involving prisoners as subjects.

(2) The UM suspended involvement of prisoners in Department of Health and Human Services (HHS) supported research projects that had not satisfied all requirements of HHS regulations at 45 CFR Part 46, Subpart C, until such requirements were satisfied.

(3) The UM has provided OHRP with a list all research protocols affected by the above referenced suspension.

(4) Furthermore, OHRP acknowledges that the UM has (i) enhanced its system for the protection of human subjects with particular regard to research involving prisoners as subjects; and (ii) adequately addressed the additional concerns raised in OHRP's July 31, 2000 letter. OHRP notes that some outstanding issues related to AIDS Clinical Trials Group (ACTG) protocols that involve prisoners are being addressed by OHRP and officials at the National Institute of Allergy and Infectious Diseases.

As a result of the above determinations, 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 these determinations.

At this time OHRP provides the following additional guidance:

(1) Regarding research involving prisoners as subjects, where the IRB finds that there may be a need for follow-up examination or care of participants **after the end of their participation**, the IRB must ensure that provisions have been made for such examination or care, taking into account of the varying lengths of individual prisoners' sentences, and for informing the participants of this fact, as required by HHS regulations at 45 CFR 46.305 (a)(7).

(2) Regarding UM's waiver of consent for protocol # 99/607 ("Prospective, Randomized Study Comparing Vascular Embolization to External Fixation in Hemodynamically Unstable Patients with Pelvic Fracture"), OHRP notes that the IRB found that the research presented no more than minimal risk to the subjects. However, OHRP notes that the IRB records do not document that the IRB made the three additional findings required by HHS regulations at 46.116(d). Where HHS regulations require specific findings on the part of the IRB, such as approving a procedure which alters or waives the requirements for informed consent, OHRP strongly recommends that all required findings be fully documented in the IRB minutes, including protocol-specific information justifying each IRB finding. It is not clear that this research would satisfy all of the requirements for waiver of informed consent under the HHS regulations at 46.116(d). OHRP recommends that the IRB re-assess its decision to approve such a waiver for protocol #99/607. OHRP is available to provide further guidance to the UM IRB concerning such waivers.

OHRP appreciates the continued commitment of your institution to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Sanford Leikin, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

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