



FOR US POSTAL SERVICE DELIVERY:

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November 13, 2000

Dr. Winfred M. Phillips
Vice President for Research
University of Florida
123 Tigert Hall
PO Box 113125
Gainesville, FL 32611-3125

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1266
Research Projects Involving Prisoners**

Dear Dr. Phillips:

The Office for Human Research Protections (OHRP) has reviewed your letters of October 2 and November 2, 2000 regarding the protection of human research subjects at the University of Florida (UF).

OHRP has determined that UF has adequately responded to all required corrective actions stipulated in OHRP's September 7, 2000 letter. In specific, OPRR finds the following:

- (1) OHRP finds that UF has revised its Policy and Procedure Manual to ensure on a permanent basis that continuing review of research involving human subjects occurs not less than one year from the date of prior review by the institutional review board (IRB), in accordance with Department of Human Services (HHS) regulations at 45 CFR 46.109(e) and the action required in OHRP's letter of September 7, 2000.
- (2) OHRP finds that UF IRB-01 and IRB-03 have amended their quorum policies to ensure that UF will not include an IRB member with a conflicting interest in its quorum count at IRB meetings, in accordance with 45 CFR 46.107(e) and the action required in OHRP's letter of September 7, 2000.
- (3) OHRP finds that UF, in accordance with the action required in OHRP's letter of September

7, 2000, has made efforts to educate IRB members concerning the requirements of 45 CFR 46.116 and, in particular, the need to draft informed consent language so that informed consent documents can be read and understood by all subjects.

(4) OHRP finds that UF has amended its IRB policy to ensure that approval of protocol changes required by the IRB is conducted by the IRB chair or a member designated by the chair, in accordance with HHS regulatory requirements of 45 CFR 46.108(b) and 46.110(b)(2).

(5) OHRP acknowledges UF's development and implementation of a plan to ensure review by an IRB member of the entire federal grant application for all active federally supported research protocols. OHRP further acknowledges UF's November 2, 2000 progress report on the status of UF's audit and review of active federally supported research and related grant applications.

Presuming full implementation of these corrective actions, 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.

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

Sincerely,



Carol J. Weil, J.D.
Division of Compliance Oversight

cc: Dr. Michael Carome, OHRP
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