



Office for Human Research Protections
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May 3, 2004

Randy P. Juhl, Ph.D.
Vice Chancellor for Research Conduct and Compliance
University of Pittsburgh
132 Cathedral of Learning
Pittsburgh, PA 15260

Susan Burkett, M.S.
Associate Provost for Research & Acad Admin
Carnegie Mellon University
5000 Forbes Avenue
Warner Hall, Room 405
Pittsburgh, PA 15213

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1259 and Federalwide Assurance FWA-4206**

Research Project: The Marriage Study
Principal Investigator: Margaret S. Clark, Ph.D.

Research Project: Study on cardiovascular health in married couples
Principal Investigators: Margaret S. Clark, Ph.D, and Wendy Troxel, M.S.

Dear Dr. Juhl and Ms. Burkett:

The Office for Human Research Protections (OHRP) has reviewed your letters dated February 25 and 26, 2004 regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research.

OHRP has determined that the corrective actions summarized below appropriately address the issues raised:

It was alleged that the researchers failed to ensure adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, as required by HHS regulations at 45 CFR 46.111(a)(7).

Corrective Action: OHRP acknowledges Carnegie Mellon University's (CMU) and University of Pittsburgh's (U Pitt) statements that no further recruitment will be undertaken in Ms. Troxel's study until a revised recruitment process and letter have been approved by the CMU and U Pitt IRBs. Such a process will involve a letter directly from Dr. Clark introducing Ms. Troxel and the new study which will be on CMU letterhead, and only Dr. Clark will subsequently contact subjects to see if they are interested in participating in Ms. Troxel's study. Ms. Troxel and Dr. Matthews will not be provided with any information about subjects until subjects give Dr. Clark consent to share that information, or contact Ms. Troxel directly. In addition, the U Pitt and CMU IRBs are enhancing their training for IRB members and researchers on confidentiality issues to help prevent such an incident in the future.

As a result, 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 institutions to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. Dennis Swanson, Director, IRB Office
Dr. Philip Troen, IRB Chair, U Pitt
Dr. Mark Lovell, U Pitt
Dr. Michael Collins, U Pitt
Margaret S. Clark, U Pitt
Ms. Susan Shingle, CMU
Dr. Ann Baldwin Taylor, CMU
Ms. Wendy Troxel, CMU
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Janice Walden, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Melinda Hill, OHRP