



Office for Human Research Protections
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April 8, 2010

Jorge V. Jose, Dr. Sci.
Vice President for Research
University at Buffalo - State University of New York
Office of the Vice President for Research
516 Capen Hall
Buffalo, NY 14260

RE: Human Research Protections Under Federalwide Assurance FWA-8824

Research Project: Parent Training and Couple Therapy in Alcohol Treatment
Principal Investigator: Frank Fincham (University of Buffalo effective 4/2/2002);
K.K. (Wendy) Lam (RTI Principal Investigator effective 11/7/06);
Antonio Morgan-Lopez (RTI Principal Investigator effective 7/12/07)
Co-Principal Investigator: William Fals-Stewart
HHS Protocol Number: R21 AA13690

Dear Dr. Jose:

Thank you for your March 26, 2010 emails in response to our February 25, 2010 letter. Based on the information submitted, we make the following determinations regarding the above-referenced research:

- (1) In our February 25, 2010 letter we determined that an investigator initiated non-exempt human subject research activities without obtaining legally effective informed consent of subjects and without the institutional review board (IRB) appropriately waiving these requirements. In response to this determination, you were asked to provide our office with a corrective action plan that will ensure that no University of Buffalo (UB) investigator will involve a human being as a subject in research covered by the regulations unless (a) the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative, or (b) the IRB has waived the requirements to obtain informed consent in accordance with Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(c) or (d), or in accordance with

the provisions for waiver of informed consent for research in emergent settings published in the *Federal Register* (61 FR 51531-51533).

Corrective Action: We note that shortly after the incidents of non-compliance occurred, UB began developing a comprehensive Human Research Subject Protection Program (HRPP). We understand that the UB HRPP uses initial and continuing education, careful protocol review using guides and checklists, and post-approval monitoring to ensure that investigators are fully aware of their responsibilities regarding the consenting of research subjects. We note further that for studies that qualify for a waiver of consent under HHS regulations at 45 CFR 46.116(c) or (d), UB IRBs utilize a waiver of consent guide to ensure that all four elements that are required to waive consent are present. We determine that these corrective actions adequately address our determination and are appropriate under the UB FWA.

- (2) In our February 25, 2010 letter we also determined that certain protocol changes were initiated without IRB review and approval, in contravention of HHS regulations at 45 CFR 46.103(b)(4)(iii). In response to this determination you were asked to provide our office with a corrective action plan that will ensure that the IRB reviews and approves all proposed changes in a research activity, during the period for which IRB approval has already been given, prior to initiation of such changes, except when necessary to eliminate apparent immediate hazards to the subjects, in accordance with HHS regulations at 45 CFR 46.103(b)(4)(iii).

Corrective Action: We acknowledge that UB has taken the following steps to address this determination:

- (a) During educational sessions, investigators are informed that any changes in research procedures must be approved by the responsible IRB using the amendment process;
- (b) UB IRB approval memorandums and the UB HRPP Policies & Procedures Manual address the requirement that no changes in research may be initiated without submission and IRB approval of an amendment to the research study;
- (c) At continuing review, investigators are asked on a Continuing Review Application Form to indicate whether any changes have occurred over the past approval period without prior IRB approval; if changes have occurred without a request for amendment having been submitted, the investigator is asked to include an amendment request form as part of their submission. This process allows inadvertent investigator omissions to be corrected at least annually before they become a continuing issue; and
- (d) Routine and for-case Quality Assurance/Quality Improvement Administrator site visits include reviewing the study file to see whether the file is in conformance with the approved protocol. When there is evidence that the investigator has unwittingly made minor changes in the conduct of the protocol, the investigator is asked to submit a protocol amendment immediately.

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We determine that these corrective actions adequately address our determination and are appropriate under the UB FWA.

At this time, there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter this determination.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator

Mr. Edward M. Zablocki, Research Subjects Protection Administrator, UB
Dr. Monica B. Spaulding, Chairperson, Health Sciences IRB #12, #14
Dr. Joel O. Raynor, Chairperson, SUNY Buffalo IRB #12, UB
Dr. Theodore I. Putnam, IRB Chairperson, IRB #16, Women and Children's Hospital, UB
Dr. Sherry Mills, National Institutes of Health (NIH)
Mr. Joseph Ellis, NIH
Dr. Sally Amero, NIH
Dr. Kenneth R. Warren, Director, National Institute on Alcohol Abuse and Alcoholism