



Office for Human Research Protections  
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February 25, 2010

Jorge V. Jose, Ph.D.  
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 email dated October 27, 2009 in response to our September 18, 2009 request that the University of Buffalo - State University of New York (UB) evaluate allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46). Based on review of your response, we make the following determinations regarding the above-referenced research:

- (1) HHS regulations at 45 CFR 46.116 state that no investigator may 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 institutional review board (IRB) has waived the requirements to obtain informed consent in accordance with 45 CFR 46.116(c) or (d). We have determined that an investigator initiated non-exempt human subject research activities without obtaining legally effective informed consent of subjects and without the IRB

appropriately waiving these requirements when investigators/investigative team members:

- (a) identified potential study participants, i.e., individuals who enrolled in community-based treatment programs and who met general eligibility criteria for the study;
- (b) retained the names of all potential subjects - regardless of whether they ultimately consented to be in the study; and
- (c) used the names of all potential subjects to access the subjects' medical records to compare characteristics of those individuals who agreed to be in the study to those who did not.

We note that according to a February 5, 2008 email from Dr. Fals-Stewart to Ms. Elyse Summers in our office, the research team obtained the informed consent of individuals who agreed to participate in the study; the research team did not obtain informed consent from those who declined study participation.

We acknowledge that your investigation revealed that the protocol, amendments and renewal materials approved by the UB IRB at no time indicated that identifiable private information would be collected from subjects prior to their consent being obtained and documented by the investigators and that there was no waiver of consent approved by the UB IRB for this method of data collection. Lastly, we note that UB IRB concluded that if such data collection did occur, it was without an approved consent process or waiver. See item (2) below.

**Corrective Action:** Please provide our office with a corrective action plan that will ensure that no 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 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).

- (2) HHS regulations at 45 CFR 46.103(b)(4)(iii) require that the IRB review and approve 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. We have 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 specific, we note that your investigation revealed that the following changes to the above-referenced research were not reviewed and approved by the UB IRB prior to implementation:

- (a) Utilization of three study interventions rather than two study interventions;

- (b) Requesting information from parents regarding Child Protective Services (CPS) involvement; and
- (c) Collection of identifiable private information from subjects without obtaining legally effective informed consent and without the IRB appropriately waiving these requirements. See item (1) above.

We note that the UB IRB reviewed the IRB file for this study and discovered that the initial IRB approval for this study (dated April 8, 2002) included the utilization of three study interventions, but that a protocol amendment changing the initial three interventions to two interventions was approved by the IRB on June 5, 2002. All subsequent materials received and reviewed by the IRB indicated that two study interventions were being utilized. The UB IRB concluded that if three interventions were utilized, as was reported in the final report for grant R21 AA13690 as well as a study manuscript entitled "Parent Training with Behavioral Couples Therapy for Fathers' Alcohol Abuse: Effects on Substance Use, Parental Relationship, Parenting and Child Protective Services (CPS) Involvement," it was without UB IRB approval. Moreover, we note that the UB IRB noted that the protocol, amendments, and renewal materials approved by the IRB at no time indicated that the investigator was going to ask parents about CPS involvement. Thus, the UB IRB concluded that if data was obtained about CPS involvement, it was without IRB approval. See the final report for grant R21 AA13690 as well as Table 5 of the above-referenced manuscript.

**Corrective Action:** Please 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).

Please forward your corrective actions so that we receive it no later than March 26, 2010. Feel free to contact me if you would like guidance in developing a corrective action plan.

We appreciate 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,

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

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Jorge V. Jose, Ph.D.-- University at Buffalo - State University of New York  
February 25, 2010

Mr. Edward M. Zablocki, Research Subjects Protection Administrator, UB

Dr. Monica B. Spaulding, Chair, Health Sciences IRB #12, #14

Dr. Joel O. Raynor, Chair, SUNY Buffalo IRB #12, UB

Dr. Theodore I. Putnam, IRB Chair, 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