



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 240-453-8120
FAX: 240-453-6909
E-mail: Lisa.Rooney@hhs.gov

February 25, 2010

E. Ward Sax, M.B.A.
V.P., Treasurer and Chief Risk Officer
Research Triangle Institute International
3040 Cornwallis Road, P.O. Box 12194
Research Triangle Park, NC 27709-2194

Ralph W. Kuncl, MD, PhD
Provost
University of Rochester
200 Wallis Hall
Box 270021
Rochester, NY 14627-0021

RE: Human Research Protections Under Federalwide Assurance FWA-3331 and 9386

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 Mr. Sax and Dr. Kuncl:

Thank you for your letters dated October 26, 2009 (Research Triangle Institute International (RTI)) and October 29, 2009 (University of Rochester) in response to our September 18, 2009 request that RTI and University of Rochester 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 the information submitted, we note that the noncompliance outlined in our September 18, 2009 letter allegedly occurred while the above-referenced research was being conducted at the University of Buffalo. As a result, we will direct any further inquiries regarding these allegations to the University of Buffalo. At

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E. Ward Sax, M.B.A.-- Research Triangle Institute
Ralph W. Kuncel, MD, PhD-- University of Rochester
February 25, 2010

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

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

Dr. Wendy A. Visscher, Chair, IRB #1 and Director, Office of Research Protection,
RTI

Ms. Angela Greene, Chair, IRB #2, RTI

Dr. Juesta M. Caddell, Chair, IRB #3, RTI

Dr. Gary L. Chadwick, Associate Provost, Director Office for Human Subject
Protection, University of Rochester

Dr. Frederick Marshall, Chair, IRB #1, #01P, University of Rochester

Dr. Steve Lamberti, Chair, IRB #2, #2P, University of Rochester

Dr. Jeanne T. Grace, Chair, IRB #3, #3P, University of Rochester

Dr. Robert DiCenzo, Chair, IRB #4, 04P, University of Rochester

Dr. Antonio Morgan-Lopez, RTI

Dr. KK Wendy Lam, Assistant Professor, University of Rochester

Dr. William Fals-Stewart, Professor, University of Rochester

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