



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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Mary T. Moore, Ph.D.
Senior Vice President
Mathematica Policy Research, Inc.
600 Maryland Ave, SW, Suite 550
Washington, DC 20024-2512

Mary Myrick, APR
Public Strategies, Inc
301 NW 63rd Street, Suite 600
Oklahoma City, OK 73116

RE: Human Research Protections Under Federalwide Assurance FWA-981

Research Project: The Building Strong Families Project
Principal Investigator: Alan M. Hershey
HHS Contract Number: 233-02-0056

Dear Dr. Moore and Ms. Myrick:

Thank you for your September 20, 2010 and December 27, 2010 letters in response to our August 10, 2010 letter informing you that the Office for Human Research Protections (OHRP) received 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.

We understand that the above-referenced study has been suspended by the funding agency for reasons unrelated to the allegations noted below. Please note that if the research is to continue, each institution that is “engaged” in human subjects research must provide OHRP with a satisfactory assurance to comply with the regulations. Please see HHS regulations at 45 CFR 46.103(a). Each “engaged” institution can provide OHRP with a satisfactory assurance by either (a) obtaining an OHRP-approved FWA; or (b) entering into a written agreement, such as an Individual Investigator Agreement (IIA), with a FWA holding institution prior to engaging in any future federally funded non-exempt human subjects research. For more information on how

the above-referenced IIA process is to work, please refer to our guidance at <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html>.

Notwithstanding this suspension, we have made the following determinations:

A. Determinations Regarding the Above-Referenced Research:

A complainant alleged that changes to the above-referenced protocol were implemented at Public Strategies, Inc. (PSI) without prior institutional review board (IRB) review and approval in violation of HHS regulations at 45 CFR 46.103(b)(4)(iii). In specific, a complainant alleged that the following changes were implemented without prior IRB review and approval:

- (1) PSI upper management allowed multiple couples with severe domestic violence documented at intake (e.g., stabbing each other, choking to the point of passing out, and a male trying to run over a female with a car) to participate in the research against the recommendation of the program's domestic violence specialist, and in violation of the protocol.
- (2) Subjects were offered \$200 to \$300 to attend just one class at PSI; an offer that was not part of the protocol or normal incentives.

Mathematica Policy Research, Inc. (Mathematica) conducted an investigation concerning the above-referenced allegations. Per Mathematica, this investigation consisted of a review of the IRB approved protocol; written procedures prepared by PSI for domestic violence screening and for program participation incentives; preliminary interviews with PSI management via telephone; on-site interviews; and a review of case and data files. Mathematica stated that the investigation did not find any indication that the alleged noncompliance occurred. Of note, Mathematica stated that it found no evidence of the following:

- That PSI upper management intervened or overruled staff decisions relating to the enrollment of couples experiencing domestic violence. According to Mathematica, PSI staff conducted domestic violence screening in accordance with the approved protocol. According to the protocol, decisions on cases involving potential subjects who had reported prior domestic violence during the intake process were made through a collaborative inter-disciplinary case review. The purpose of the inter-disciplinary group was to discuss whether a potential subject's circumstances would warrant exclusion from the program and if so, what referrals or follow-up should be taken to ensure safety. Mathematica's investigation found that decisions involving potential subjects who had reported prior domestic violence during the intake process were made collaboratively by designated staff, not by upper management.
- That couples were offered \$200 to \$300 to attend just one class. According to Mathematica, the approved protocol specified that PSI would encourage participation in the program being studied. Consistent with this provision of the protocol, PSI developed

a schedule of cash incentives for participation in the program; these incentives totaled a maximum of \$200, with payments of \$100 after two sessions, \$50 after four, and \$50 after completion of all sessions. According to Mathematica's investigation, this incentive plan was carefully adhered to. Mathematica found no evidence that the above-referenced plan was not followed and that staff paid cash incentives larger than \$100 per session to any participants.

Based on the information noted above, we have determined that this allegation of noncompliance could not be proven.

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.

We appreciate your institution's continued commitment to the protection of human research subjects.

Sincerely,

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

cc:

Ms. Anne Ciemnecki, Associate Director for Survey, Mathematica Policy Research, Inc.
Mr. David Bernhardt, IRB Chairperson, Public/Private Ventures
Mr. Alan M. Hershey, Mathematica Policy Research, Inc.
Mr. David Hansell, Acting Assistant Secretary, Administration for Children and Families
Ms. Nancye Campbell, Office of Planning, Research and Evaluation, Administration for Children and Families