DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 240-453-8132
FAX: 240-453-6909
E-mail: Kristina.borror@hhs.gov

May 2, 2008

Leslie P. Tolbert, Ph.D.
Vice President for Research and Graduate Studies
University of Arizona
601 Administration Building
Tucson, AZ 85721

RE: Human Subjects Protections Under Federalwide Assurance FWA-4218

Research Project: **Mediumistic Investigation of Identity Survival and other research projects involving mediums**

Principal Investigator: **Gary Schwartz, Ph.D.**

Dear Dr. Tolbert:

Thank you for your January 31, 2008 letter that was submitted in response to our December 19, 2007 letter regarding the above-referenced research.

In our June 22, 2007 letter, we made the following determination, among others:

(1) We determined that the principal investigator for the above-referenced research initiated changes to the research without institutional review board (IRB) review and approval, and as a result, failed to protect the privacy of subjects and to maintain the confidentiality of data. As part of your corrective action, you indicated that the principal investigator will no longer disclose the names of any research subject publicly without their written consent. In our December 19, 2007 letter we noted that the principal investigator continued to disclose the names of research subjects publicly.

Corrective Action: We acknowledge your statement that the Vice President for Research, Graduate Studies, and Economic Development at the University of Arizona (UA) will issue a letter of reprimand to the principal investigator. This letter will also reiterate the continuing requirement to protect the privacy of subjects and the confidentiality of data, and that the PI must refrain from disclosing the names of any research subject publicly without the subject's written consent. Copies of the letter will be sent to the principal investigator's Department Head and Dean. This corrective action adequately addresses our determination.

OHRP makes the following additional determinations:

(2) Department of Health and Human Services (HHS) regulations at 45 CFR 46.111(b) require that in order to approve research, the IRB shall determine that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

We note your statement that sitters were not to be enrolled unless at least one year had passed since the death of the sitters' loved one in order to safeguard the potential sitter from undue influence and in recognition of the potential sitter's vulnerability after the recent passing of a loved one. We also note your statement that the research protocol did not include this information and that this information was not presented to the IRB. We also note that one subject was contacted by the principal investigator to recruit for research at least as early as five months after the death of a loved one, and one subject was contacted to recruit for research at least as early as three months after the death of a loved one, in contravention of the policy stated above.

We determine that the protocol did not include additional safeguards for subjects who have recently lost a loved one, and therefore may have been vulnerable to coercion or undue influence.

Corrective Action: We acknowledge your statement that in the event that future studies occur in which subjects have experienced a loss, it will be required that the principal investigator address the vulnerability of the subjects and that vulnerability will be considered by the IRB in its review of the research. This action adequately addresses our determination.

(3) One complainant alleged that one of the purposes of the research was fund-raising for Dr. Schwartz but that this was not disclosed to subjects, in contravention of HHS regulations at 45 CFR 46.116(a)(1). You stated that the UA investigative panel found no evidence of funding irregularities or of Dr. Schwartz's solicitation of funds from research subjects. We therefore determine that the allegation is unproven.

(4) One complainant alleged that highly sensitive, identifiable research data was sent by Dr. Schwartz to the complainant without receipt request for signature or a way to track the package; the package and its contents were lost, along with the

identifiable private information about the subject. UA acknowledges this and states that the package was likely lost after it left UA. We determine that failure to send the data in question without receipt request for signature or a way to track the package is not a violation of HHS regulations at 45 CFR part 46.

(5) One complainant alleged that Dr. Schwartz conducted research with her without prior IRB review and approval or informed consent. We could find no evidence that this complainant was a subject in research conducted by Dr. Schwartz. Therefore we determine that this allegation is unproven.

As a result, there should be no need for further involvement of our office in this matter. Of course, we must be notified should new information be identified 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,

Kristina C. Borror, Ph.D.
Director,
Division of Compliance Oversight

cc:
Dr. Rebecca Dahl, Program Director, Human Subjects Protection Program, UA
Dr. David Johnson, Chair, IRB #1 and #3, UA
Dr. Theodore Glattke, Chair, IRB #2, UA
Dr. Linda Garland, Chair, IRB #3, UA
Dr. Gary Schwartz, UA