DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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June 22, 2007

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:	**Mediunistic Investigation of Identity Survival and other research projects involving mediums**
Principal Investigator:	**Gary Schwartz, Ph.D.**

Dear Dr. Tolbert:

The Office for Human Research Protections (OHRP) has reviewed the University of Arizona's (UA) August 25, 2006 report that was submitted in response to OHRP's April 14, 2006 letter regarding the above-referenced research.

Based on a review of the UA August 25, 2006 report, OHRP makes the following determinations:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b) and 46.109(a), require that the institutional review board (IRB) review and approve all non-exempt human subject research covered by an assurance. OHRP notes that the August 18, 2006 report of the Blue Ribbon Investigation Panel states:

(a) "Examples 14 – 16 correspond to instances where identities were revealed in three articles published in the *Journal of the Society for Psychical Research*. Names were revealed where IRB approval was not obtained and consent not documented."

(b) "In Examples 14, 15, and 16. Dr. Schwartz conducted human subjects research without IRB approval."

OHRP finds that certain human subjects research, as noted in Examples 14-16 of the August 25, 2006 UA report, conducted by Dr. Schwartz and published in the *Journal of the Society for Psychical Research*, was conducted without IRB review and approval.

(2) HHS regulations at 45 CFR 46.117(a) require that informed consent be documented by the use of a written consent form approved by the IRB and that is signed by the subject, or the subject's legally authorized representative, unless the IRB waives this requirement. Based on the information provided in the report of the Blue Ribbon Investigation Panel (see (1), *supra*), OHRP finds that informed consent was not documented by a written consent form signed by the subjects for research conducted by Dr. Schwartz and published in the *Journal of the Society for Psychical Research* and the UA IRB did not approve a waiver of the requirement to document informed consent for this research.

(3) HHS regulations at 45 CFR 46.111(a) require that in order to approve research covered by the HHS regulations the IRB must determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. HHS regulations at 45 CFR 46.103(b)(4) require that institutions follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects. OHRP notes that August 18, 2006 report of the Blue Ribbon Investigation Panel states:

(a) "Examples 12 and 13 discuss mediumship readings with [complainant] as a sitter.

These are instances where Dr. Schwartz had obtained signed consent forms promising confidentiality but released the names of individuals in publications."

(b) "In examples 12 and 13, Dr. Schwartz conducted human subjects research with IRB approval. The names of two subjects who participated in the study were revealed publicly, contrary to the conditions of the written informed consent."

OHRP finds that the principal investigator for the above-referenced research with respect to examples 12 and 13, initiated changes to the research without IRB review and approval, and as a result, failed to protect the privacy of subjects and to maintain the confidentiality of data.

Corrective Actions: OHRP notes that UA recommended that, (i) the principal investigator remove the names of any subjects who have not approved the use of their names from websites he authors; (ii) the principal investigator no longer disclose the

names of any research subject publicly without their written consent; (iii) the principal investigator submit all human subjects research he conducts to the UA IRB for review and approval; and (iv) all of the principal investigator's current studies be suspended until the investigator completes humans subjects protection training.

Required Action: OHRP requests that UA provide an update on the extent to which the above corrective actions have been implemented. As part of your report, please provide a list of all human subjects research conducted by the principal investigator since August 2006.

At this time, OHRP has the following additional questions and concerns:

(4) [Redacted]

(5) [Redacted]

(6) [Redacted]

Please forward your response to the above required action and additional concerns no later than August 1, 2007.

OHRP appreciates 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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

Enclosure

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
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