**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Office of the Secretary**
**Office of Public Health and Science**

**Office for Human Research Protections**
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December 19, 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:** **Mediumistic 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) July 31, and October 10, 2007 reports that were submitted in response to OHRP's April 14, 2006 and September 6, 2007 letters regarding the above-referenced research.

Based on its review, OHRP makes the following determination:

(1) UA has confirmed and OHRP finds that the human subjects research described in the article entitled "Evidence of Anomalous Information Retrieval between Two Research Mediums: Telepathy, Network Memory Resonance, and Continuance of Consciousness" [Schwartz, G.E.R. and Russek, L.G.S. (2001) *JSPR* 65.4, 257-275] was conducted without institutional review board (IRB) review and approval in contravention of Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b) and 46.109(a).

**Corrective Action:** OHRP acknowledges that the research was conducted prior to the time that Dr. Schwartz was counseled that such studies require IRB approval. OHRP acknowledges UA's statement that Dr. Schwartz currently submits all human subjects research he conducts to the UA IRB for review and approval, and that he completed human subject protections training on September 18, 2006.

OHRP finds that these corrective actions adequately address the finding and are appropriate under the UA FWA.

(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. In its September 6, 2007 letter, OHRP expressed concern that the principal investigator failed to provide a subject enrolled in the above-referenced research with copies of the readings in which the subject participated, as was described in the informed consent document. OHRP noted that the informed consent document signed by the subject states:

> "The content of my interviews and readings will only be available to the investigators of the VERITAS Research Program of the Human Energy Systems Laboratory in the Department of Psychology at the University of Arizona. In addition, I or the sitter may request a copy of the reading."

OHRP finds that a subject requested a copy of the reading in which she participated, but was not provided with the reading, in contravention of HHS regulations at 45 CFR 46.103(b)(4)(iii).

**Corrective Action:** OHRP acknowledges that the subject had participated in screening readings, not research readings, and UA did not anticipate subjects requesting copies of their screening readings. UA has indicated that copies of the screening readings will also now be made available to subjects requesting such copies. OHRP is aware that the subject has received a transcript of the screening readings in which she participated. OHRP finds that UA's responses adequately address the above finding.

In its June 22, 2007 letter, OHRP made the following determination, among others:

(3) OHRP found that the principal investigator for the above-referenced research 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. As part of UA's corrective action, you indicated that the principal investigator will no longer disclose the names of any research subject publicly without their written consent. OHRP notes that the principal investigator continues to disclose the names of research subjects publicly (see attached).

**Required Action:** By February 2, 2008 please provide OHRP with additional corrective actions to address this finding.

OHRP has the following additional concerns:

(4) [Redacted]

Please provide OHRP with a response to the above required action and concern by February 2, 2008.

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,

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

Enclosure

cc with attachments:
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

cc without attachments:
Dr. Ivor Pritchard, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms Shirley Hicks, OHRP