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: 240 453-8297
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January 25, 2005

Arthur C. Vailas, Ph.D.
Vice President for Research
University of Houston
4800 Calhoun
316 East Cullen
Houston, TX 77204-2015

**RE: Human Research Subject Protections Under Federalwide Assurance FWA-5994**

**(1) Research Project: "Investigation of Variables Involved in the Behavioral Treatment of Children with Autism"**
**Project Number: 03-097**
**Principal Investigator: Gerald Harris, Ph.D.**

**(2) TYAP Project: Acquisition of ABA Treatment Skills: In-Vivo vs. Video Modeling**

**(3) Research Project: Generalization of Parent Training: A Comparison Study**
**Principal Investigator: Gerald Harris, Ph.D.**

**(4) Research Project: Training and Generalizing Interaction Skills with Siblings of Children with Autism**
**Principal Investigator: Gerald Harris, Ph.D.**

**(5) Research Project: The Relationship of Parental Stress to Autism Treatment Type and Duration**
**Principal Investigator: Gerald Harris, Ph.D.**

Dear Dr. Vailas:

The Office of Human Research Protections has received the University of Houston's (UH) January 27, 2005 report responding to OHRP's December 14, 2004 inquiry regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects involving the above-referenced research.

OHRP has the following questions and concerns about the above-referenced research:

(1) [Redacted]

(2) [Redacted]

(3) [Redacted]

(4) [Redacted]

OHRP makes the following finding regarding UH IRB Policies and Procedures.

(5) HHS regulations at 45 CFR 46.103(a), 46.103(b)(4)(ii) and 46.103(b)(5) require that institutions have written IRB procedures that adequately describe IRB operations with respect to:

(a) determining which projects require review more often than annually and which need verification from sources other than the investigators that no material changes have occurred since previous IRB review, and

(b) ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

OHRP finds that the UH IRB Policies and Procedures supplied to OHRP do not contain specific procedures for how the IRB conducts these activities.

**Required Action:** Please provide OHRP with a copy of revised written UH IRB Policies and Procedures that include the above-described required elements of written IRB procedures set forth at 45 CFR 46.103(b)(4)(ii) and (iii) and (5). OHRP guidance on developing such written IRB procedures may be found at http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm.

Please respond to the above required actions, questions, and concerns by February 15, 2006. If you identify additional noncompliance in preparing your response to OHRP, please provide a description of any corrective actions that have been or will be taken to address such noncompliance.

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,

Carol J. Weil, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Ms. Debra Comeaux, Research Compliance Specialist, U Houston
Dr. Merrill Hiscock, IRB Chair, U Houston IRB #2A and 2B
Dr. Gerald Harris, U Houston
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Janet Fant, OHRP