

Office for Human Research Protections The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, Maryland 20852 Telephone: 240 453-8297 FAX: 240 453-6909

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) <u>Research Project</u>: "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) <u>Research Project</u>: Generalization of Parent Training: A Comparison Study Principal Investigator: Gerald Harris, Ph.D.

(4) <u>Research Project</u>: Training and Generalizing Interaction Skills with Siblings of Children with Autism

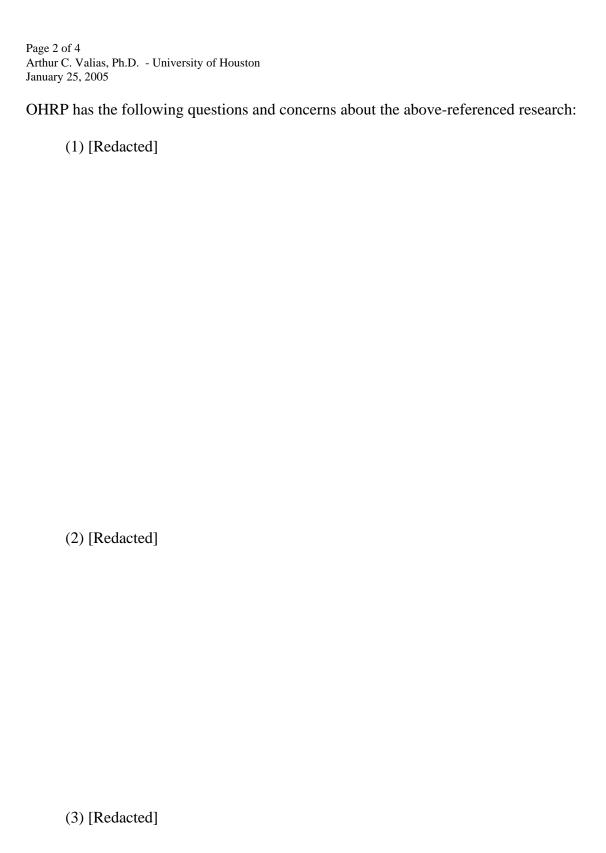
Principal Investigator: Gerald Harris, Ph.D.

(5) <u>Research Project</u>: 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.



(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.

Page 4 of 4 Arthur C. Valias, Ph.D. - University of Houston January 25, 2005

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