



Office for Human Research Protections  
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July 31, 2002

Ralph Snyderman, M.D.  
President  
Duke University Health System, Inc.  
Box 3001  
Durham, North Carolina 27710

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1106**

**Research Project: Preferences Among Teenage Inhalant Abusers**  
**Investigator: Dr. Pedro Weisleder, Division of Pediatric Neurology**

Dear Dr. Snyderman:

The Office for Human Research Protections (OHRP) has reviewed your July 16, 2002 report responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research that were presented in OHRP's May 21, 2002 letter.

The allegations involved the following:

The research, involving 35 male subjects detained in a juvenile correction facility in Arizona, was conducted without the review of one of the Duke University Health System, Inc. (DUHS) institutional review boards (IRBs), as required by HHS regulations at 45 CFR 46.109(a) and the DUHS MPA. As a result, the research failed to satisfy the requirements of HHS regulations at 45 CFR 46.111, and Subparts B and C of 45 CFR Part 46.

Based upon its review of your report, OHRP finds no evidence to substantiate the above allegations. In particular, OHRP acknowledges that the above-referenced research was conducted by the principal investigator while he was an employee of another institution and prior to becoming an employee of DUHS. As a result, the research was not covered by the DUHS MPA and did not require review by one of the DUHS IRBs.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP acknowledges that (i) the research was not Federally supported or conducted, nor conducted under an applicable OHRP-approved assurance of compliance; and (ii) since joining DUHS, the principal investigator has received training regarding the ethical principles and regulatory requirements related to human subjects research.

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,

Michael A. Carome, M.D.  
Director, Division of Compliance Oversight

cc: Dr. John M. Falletta, Chair, IRB-01, DUHS  
Ms. Charlotte Coley, IRB Administrator, DUHS  
Dr. Pedro Weisleder, DUHS  
Dr. Greg Koski, OHRP  
Dr. Melody H. Lin, OHRP  
Dr. Jeffrey Cohen, OHRP  
Mr. George Gasparis, OHRP  
Ms. Janice Walden, OHRP  
Mr. Barry Bowman, OHRP