



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary  
Office of Public Health and Science

**FOR US POSTAL SERVICE DELIVERY:**

Office for Human Research Protections  
6100 Executive Boulevard, Suite 3B01  
Institutes of Health (MSC 7507)  
Rockville, Maryland 20892-7507

**FOR HAND DELIVERY OR EXPRESS MAIL:**

Office for Human Research Protections  
6100 Executive Boulevard, Suite 3B01 National  
Rockville, Maryland 20852

Telephone: 301-402-5567  
FAX: 301-402-2071  
E-mail: mc2a@nih.gov

August 20, 2001

Neal Nathanson, M.D.  
Vice Provost for Research  
110 College Hall  
University of Pennsylvania  
Philadelphia, PA 19104

Mary Chatterton, J.D.  
Secretary  
Monell Chemical Senses Center  
3500 Market Street  
Philadelphia, PA 19104-3308

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M1025**

**Research Project: Perception of Acetone; IRB #192101**

**Principal Investigator: Charles J. Wysocki**

**HHS Project Numbers: RO1 DC-00298; P50 DC00214; F32 DC-00197**

Dear Dr. Nathanson and Ms. Chatterton:

The Office for Human Research Protections (OHRP) has reviewed your July 25, 2001 report regarding the above referenced research that was submitted in response to OHRP's June 20, 2001 letter.

Based upon its review, OHRP finds that the University of Pennsylvania (U Penn) and Monell Chemical Senses Center (Monell) have developed a satisfactory plan for debriefing subjects who participated in the above referenced research. In particular, OHRP acknowledges that the debriefing text provided with your letter includes the following: (i) an accurate explanation of the purpose of the research; (ii) a simple, complete, and accurate description of all research procedures that the subjects underwent; (iii) the names and approximate levels of all chemicals to which the subjects were exposed, and the known exposure safety limits for each chemical; (iv) a description of the reasonably foreseeable risks and discomforts of the research; (v) a description of any benefits to the subjects or others that may have resulted from the research; and (vi) an explanation of whom to contact if the subjects have any questions about their rights as

research subjects. Furthermore, OHRP acknowledges that U Penn and Monell have developed an adequate plan to help subjects cope with, and recover from, any anxiety that may be engendered by the debriefing process.

OHRP notes that the debriefing text provided with your letter is directed at factory worker subjects who participated in the above referenced research. OHRP presumes that similar debriefing texts have been or will be prepared for the *non-factory workers exposed to acetone* and the *non-acetone exposed subjects* who participated in either Study I (“Determining the Irritation Threshold for Acetone: Detection and Lateralization Study”) or Study II (“Evaluating the Perceptual Response to Acetone: Judgements of Intensity and Irritation”) of the above referenced protocol. OHRP requests that U Penn and Monell submit to OHRP a representative debriefing letter sent to each group of subjects (with redaction of all subject identifiers) as soon as the letters are issued.

Presuming full implementation of the debriefing plan by U Penn and Monell for all three groups of subjects who participated in the above-referenced research, there should be no need for further involvement of OHRP in this matter. As a result, OHRP is closing its compliance oversight evaluation of the above-referenced research. Of course, OHRP must be notified should new information be identified which might alter the above determination.

OHRP appreciates your institutions’ commitment to the protection of human 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. Greg Koski, OHRP  
Dr. Melody Lin, OHRP  
Mr. George Gasparis, OHRP  
Ms. Roslyn A. Edson, OHRP  
Dr. Jeffrey Cohen, OHRP  
Mr. Barry Bowman, OHRP  
Dr. Joseph Sherwin, Director of Regulatory Affairs, U Penn  
Dr. Nicholas Kefalides, IRB Executive Chair, U Penn  
Dr. Charles J. Wysocki, Monell  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA