



**FOR US POSTAL SERVICE DELIVERY:**

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August 7, 2000

Donald C. Harrison, M.D.  
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Provost for Health Affairs  
University of Cincinnati  
P.O. Box 670663  
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Elliot G. Cohen  
Senior Vice President  
University Hospital  
234 Goodman  
Cincinnati, OH 45219-2316

Gary N. Nugent, MHA  
Medical Center Director  
VA Medical Center  
3200 Vine Street  
Cincinnati, OH 45220

Glenn D. Warden, M.D.  
Chief of Staff  
Shriners Burns Institute  
3229 Burnet Avenue  
Cincinnati, OH 45229

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)  
M-1138**

**Research Project: Biology of Schizophrenia Subtypes-II (Garver)  
Principal Investigator: David L. Garver, M.D.**

**Research Project: Lack of enhance response to repeated d-amphetamine challenge in  
first-episode psychosis: implications for a sensitization model of psychosis in humans.  
Strakowski SM, Sax KW, Setters MJ, Stanton SP, and Keck PE. Biol Psychiatry  
1997;42:749-755 (Strakowski)  
Principal Investigator: Stephen M. Strakowski, M.D.**

**HHS Project Number: M01 RR08084**

Dear Dr. Harrison, Mr. Cohen, Mr. Nugent, and Dr. Warden:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your submissions of October 28, 1999, and June 23, 2000, regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR 46, and the University of Cincinnati's (UC) Multiple Project Assurance.

OHRP finds that UC has implemented the corrective actions required by OHRP as a result of the investigations of the above-referenced protocols. These actions were outlined in detail in OPRR's correspondence of September 23, 1999. (For ease of reference, a copy of that letter is enclosed.) Therefore, with respect to the above-referenced protocols, 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. Moreover, please note that this determination has no bearing on the status or disposition of other UC compliance matters currently under investigation by OHRP.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me if you have any questions.

Sincerely,



Elyse I. Summers, J.D.  
Division of Human Subject Protections

Enclosure: OPRR Correspondence (September 23, 1999)

cc: Dr. Harry Rudney, IRB-01 Co-Chair, UC  
Dr. Peter Frame, IRB-01 Co-Chair, UC  
Ms. Carolyn West, UC IRB-01 Administrator  
Dr. John Mather, Department of Veterans Affairs  
Dr. Melody Lin, OHRP  
Dr. J. Thomas Puglisi, OHRP  
Dr. Michael A. Carome, OHRP  
Ms. Roslyn Edson, OHRP  
Dr. Katherine Duncan, OHRP  
Dr. Jane E. Henney, FDA  
Dr. David Lepay, FDA  
Dr. James McCormack, FDA