



Office for Human Research Protections  
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November 13, 2002

Steven Knapp  
Provost and Vice President for Academic Affairs  
The Johns Hopkins University  
Office of the Provost  
265 Garland Hall  
3400 N. Charles Street  
Baltimore, MD 21218-2692

**RE: Human Research Subject Protections Under Multiple Project Assurance  
(MPA) M-1091**

**Research Activity: Study of Tetramethyl (M<sub>4</sub>N) and GlycinyI (G<sub>4</sub>N)  
Derivatives of Nor-Dihydroguaiarectic Acid for Oral  
Cancer Treatment in India**

**Principal Investigator: Dr. Ru Chih Huang**

Dear Dr. Knapp:

The Office for Human Research Protections (OHRP) has received The Johns Hopkins University's (JHU) July 24, 2002 report, as well as your November 11, 2002 letter, that were submitted in response to OHRP's June 18, 2002 letter regarding the above-referenced research.

OHRP finds that the following corrective actions taken by JHU adequately addresses the findings and required actions stipulated by OHRP in its June 18, 2002 letter:

- (1) JHU has provided a revised Part 3 of its MPA signed by a new Authorized Institutional Official.
- (2) JHU has put into place procedures for submitting clinical studies for review through the

Homewood institutional review board (IRB) to the Joint Committee on Clinical Investigation at the JHU School of Medicine.

(3) JHU has developed new IRB procedures addressing OHRP's determinations.

(4) JHU has committed to providing more easily accessible information regarding human subjects protections and has expanded its website to enable investigators to obtain detailed information related to policies and training opportunities.

As a result of the above determination, 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 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,

Patrick J. McNeilly, Ph.D.  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc: Dr. Richard E. McCarty, Krieger School of Arts and Sciences  
Mr. Marc D. Donohue, Associate Dean for Research, Whiting School of Engineering  
Dr. Robert Sirota, Director, Peabody Institute  
Mr. Stephen Szabo, Interim Dean, School of Advanced International Studies  
Dr. Theodore Poehler, Vice Provost for Research  
Dr. Gary Ostrander, Associate Provost for Research  
Mrs. Estelle Fishbein, JHU  
Mr. Frederick Savage, JHU  
Dr. Howard Egeth, JHU  
Dr. Ru Chih C. Huang, JHU  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. Greg Koski, OHRP  
Dr. Melody Lin, OHRP  
Dr. Michael A. Carome, OHRP  
Dr. Jeffrey Cohen, OHRP  
Mr. George Gasparis, OHRP  
Dr. Harold Blatt, OHRP

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**Mr. Barry Bowman, OHRP**