DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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December 14, 2001

Chi Van Dang, M.D., Ph.D.
Vice Dean for Research
The Johns Hopkins University
School of Medicine
School of Medicine Administration Building, Room 124
720 Rutland Avenue
Baltimore, MD 21205-2196

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1011

Research Project:	**A Comparison of Levomethadyl Acetate, Buprenorphine, and Methadone for Opioid Dependence (N. Engl. J. Med. 2000; 343:1290-7)**
HHS Project #:	**P50 DA05273, K02 DA00332, K05 DA00050**
PI:	**Dr. Rolley E. Johnson**

Dear Dr. Dang:

The Office for Human Research Protections (OHRP) has reviewed your March 23, 2001 report involving the above-referenced research. Based upon its review of the materials submitted with your report, OHRP finds no evidence to substantiate the allegations set forth in OHRP's letter of January 22, 2001. OHRP notes the following:

(1) The above-referenced research was reviewed by the Johns Hopkins Bayview Medical Center (JHBMC) Institutional Review Board (IRB) at a convened meeting on September 18, 1995. The discussion related to this protocol focused primarily on the ethical question of using a low dose of methadone in the study. This discussion included such topics as the prior research performed by the investigator, past literature on opioid addiction treatment, community use of low dose methadone, and other variables that influence outcomes in drug addiction treatment.

(2) During the September 18, 1995 meeting, the JHBMC IRB approved the protocol and required that the investigator revise the informed consent document to provide a description of the risks associated with all arms of the study. As a result, statements were added to the informed consent document that all study treatments may not be equally effective in controlling substance abuse behavior and that subjects may continue use illicit drugs and engage in high risk behaviors such as needle sharing.

In addition, the JHBMC IRB required that the investigator provide a detailed exit criteria whereby subjects having inadequate response to therapy would be withdrawn from the study. As a result, the investigator developed criteria to identify subjects who are having inadequate response to the study therapy and would be withdrawn from the study.

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. Michael Klag, Vice Dean for Clinical Investigations, JHUSOM
Mr. Ronald R. Peterson, President, The Johns Hopkins Hospital
Dr. Sue K. Donaldson, Dean, School of Nursing, JHU
Dr. Jacquelyn Campbell, School of Nursing, JHU
Ms. Karen Cox, Research Administrator, Kennedy Krieger Institute

Dr. Darrell R. Abernethy, Clinical Director, NIA
Mr. Richard P. Suess, Chief of Staff, Applied Physics Laboratory
Mr. David Grant, Applied Physics Laboratory
Ms. Barbara L. Starklauf, Administrator, Human Subjects Committees, JHUSOM
Dr. Lewis Becker, Chairman, JCCI -I, JHUSOM
Dr. David R. Cornblath, Chairman, JCCI-II, JHUSOM
Dr. Paul Lietman, Chairman, JCCI-III, JHUSOM
Dr. Paul Braine, Chairman, JCCI-IV, JHUSOM
Dr. Gary Briefel, Chairman, JHBMC-1 IRB
Dr. Judith Stiff, Chairman, JHBMC-2 IRB
Commissioner, FDA
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Dr. Greg Koski, OHRP
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Dr. Michael A. Carome, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Harold Blatt, OHRP
Mr. Barry Bowman, OHRP