



Office for Human Research Protections  
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July 24, 2002

Jianhua Li, M.D.  
Deputy Director, Professor of Psychiatry  
Yunnan Institute for Drug Abuse  
Xi-Hua-Yuan, Kunming 650228  
Yunnan Province, China

**RE: Human Research Subject Protections Under Federalwide Assurance FWA-2238**

**Research Project: Molecular Genetics of Heroin Dependence**  
**Principal Investigator: Dr. Ming T. Tsuang**  
**HHS Project Number: R01 DA12846**

Dear Dr. Jianhua Li:

The Office for Human Research Protections (OHRP) has reviewed your May 4, 2002 report regarding the above referenced research conducted at the Yunnan Institute for Drug Abuse (YIDA) that was submitted in response to OHRP's March 28, 2002 letter.

In its March 28, 2002 letter, OHRP expressed concern that the informed consent document approved by the YIDA Institutional Review Board (IRB) stated a different volume of blood drawn than the protocol indicated. OHRP acknowledges that, for technical reasons, the investigators obtained less blood than was originally called for in the protocol and the informed consent document. The informed consent document then was revised and approved by the YIDA IRB, and the subjects already consented were re-consented.

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 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,

Kristina C. Borrer, Ph.D.  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc: Dr. Ming T. Tsuang, MMHC  
Lester Grinspoon, MMHC  
Dr. Ramon Greenberg, IRB Chair, MMHC  
Mr. Ma Kejian, IRB Chair, YIDA  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. Melody H. Lin, OHRP  
Dr. Michael A. Carome, OHRP  
Mr. George Gasparis, OHRP  
Ms. Yvonne Higgins, OHRP  
Mr Barry Bowman, OHRP