



Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 301-435-8072
FAX: 301-402-2071
E-mail: kborror@osophs.dhhs.gov

July 24, 2002

Sun Bi-Xiong, M.D.
President
Shanghai No. 1 Textile Hospital
1291 Jiang-Ning Road
Shanghai 200060 China

RE: Human Research Subject Protections Under Single Project Assurance (SPA) S-14309-01

Research Project: Longitudinal Investigation of Respiratory Disease in Chinese Textile Workers

Principal Investigator: Dr. David C. Christiani

HHS Grant Number: OH02421

Dear Dr. Sun Bi-Xiong:

The Office for Human Research Protections (OHRP) has reviewed your April 17, 2002 report regarding the above referenced research conducted at the Shanghai No. 1 Textile Hospital (STH) that was submitted in response to OHRP's March 28, 2002 letter.

Based on its review, OHRP makes the following determination:

Department of Health and Human Services (HHS) regulations at 45 CFR 46.117(c) require specific findings on the part of the Institutional Review Board (IRB) for waiver of the usual requirements for the investigator to obtain a signed consent form from all subjects. OHRP's review of IRB documents reveals no evidence that the STH IRB made the required findings when approving a waiver for the above-referenced research.

Corrective Action: OHRP acknowledges that for future studies the STH will require written

informed consent. OHRP also acknowledges that the STH IRB has adopted the use of a worksheet for waiver of written consent and now is documenting in its meeting minutes the findings for waiver of written informed consent. The investigators also have completed human subject training. These corrective actions adequately address the above finding and are appropriate under the institution's SPA.

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: Commissioner, FDA
Dr. David Lepay, FDA
Mr. John H. Lichten, HSPH
Ms. Sarah Putney, HSPH
Dr. Troyen A. Brennan, Chair, IRB, HSPH
Dr. David Christiani, HSPH
Dr. Xiping Xu, HSPH
Dr. Xiao Yi-jia, IRB Chair, Shanghai No. 1 Textile Hospital
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Mr. George Gasparis, OHRP
Ms. Yvonne Higgins, OHRP
Mr. Barry Bowman, OHRP