



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: [kborrow@osophs.dhhs.gov](mailto:kborrow@osophs.dhhs.gov)

October 6, 2003

Aram V. Chobanian, M.D.  
Medical Campus Provost  
Boston University Medical Center  
715 Albany Street  
Boston, MA 02118-2526

**RE: Human Research Subject Protections Under Federalwide Assurance FWA– 301**

**Research Project:** An Evaluation of the Thalidomide Fetal Exposure Prevention Program

**Principal Investigator:** Allen Mitchell, M.D.

**BUMC Project Number:** E4403

Dear Dr. Chobanian:

The Office for Human Research Protections (OHRP) has reviewed your report of August 2, 2002 regarding the above-referenced research conducted at the Boston University Medical Center (BUMC). OHRP apologizes for our delay in responding to your report.

Based upon its review of your report and communications with the Food and Drug Administration, OHRP finds that the outstanding questions and concerns have been resolved. As a result, OHRP anticipates no need for further involvement with BUMC related to this matter.

At this time, OHRP provides the following guidance:

Written IRB policies and procedures should provide a step-by-step description with key operational details for each of the procedures required by Department of Health and Human Services regulations at 45 CFR 46.103(b)(4) and (5) (see <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm> for guidance.)

OHRP appreciates your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,

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

cc: Dr. Jonathan Woodson, IRB Chair IRB#1, BUMC  
Dr. Louis Vachon, IRB Chair IRB#2, BUMC  
Dr. Richard Saitz, IRB Chair IRB#3, BUMC  
Dr. Susan Fish, IRB Director, BUMC  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. Edward Cox, FDA  
Dr. Bernard Schwetz, OHRP  
Dr. Michael A. Carome, OHRP  
Dr. Melody H. Lin, OHRP  
Ms. Shirley Hicks, OHRP  
Ms. Yvonne Higgins, OHRP  
Ms. Patricia El-Hinnawy, OHRP  
Ms. Melinda Hill, OHRP