



FOR US POSTAL SERVICE DELIVERY:

Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:

Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01 National
Rockville, Maryland 20852

Telephone: 301-435-0668
FAX: 301-402-2071
E-mail: mceillp@od.nih.gov

July 11, 2001

Jack O. Burns, Ph.D.
Vice Provost for Research
Office of Research
University of Missouri-Columbia
205 Jesse Hall
Columbia, MO 65211

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1502

Research Activity: Curtis, JJ, *et al.* Continuous Warm Blood Cardioplegia: A Randomized Prospective Clinical Comparison. *International Journal of Angiology*. 5:212-218; 1996.

Dear Dr. Burns:

The Office for Human Research Protections (OHRP) has reviewed the report from Dr. Robert Hall dated July 5, 2001 regarding the above referenced research. Based on the documents provided in this report, OHRP acknowledges the following corrective action taken by the University of Missouri-Columbia (UMC):

UMC has developed a satisfactory plan to contact all surviving subjects (or relatives of all deceased subjects) of the above referenced research. UMC has also provided OHRP with copies of letters used to debrief subjects or their surviving relatives as requested in OHRP's May 10, 2001 letter.

OHRP finds that the corrective action described above, as well as those described in UMC's February 22, 2001 report, adequately address the issues raised in OHRP's November 22, 2000 letter to UMC. As a result, there should be no need for further involvement of OHRP in this matter.

Page 1 of 2
University of Missouri-Columbia - Dr. Jack O. Burns
July 11, 2001

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 questions.

Sincerely,

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

cc: Dr. Charles M. Borduin, Chair, IRB-01XM., UMC
Dr. L. Wayne Hess, Chair, IRB-02, UMC
Dr. Robert Hall, UMC
Dr. Jack Curtis, UMC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. John Mather, ORCA, Department of Veterans Affairs
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Ms. Roslyn Edson, OHRP
Mr. Barry Bowman, OHRP