



Office for Human Research Protections
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October 6, 2003

M. Ian Phillips, Ph.D., D.Sc.
Vice President for Research
University of South Florida
4202 E. Fowler Ave., ADM 200
Tampa, FL 33620-5950

Richard A. Silver
Director
James A. Haley Veterans Hospital
13000 Bruce B. Downs Boulevard
Tampa, FL 33612

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)
M-1284 and Federalwide Assurance (FWA) 00001669**

**Research Activity: Research Conducted in the Division of Thoracic and
Cardiovascular Surgery**
Principal Investigator: Dimitri Novitzky, M.D.

Dear Dr. Phillips and Mr. Silver:

The Office for Human Research Protections (OHRP) has reviewed the University of South Florida's (USF) September 29, 2003 report in response to OHRP's letter of August 7, 2003 regarding the above-referenced research.

Base upon its review of your report, OHRP finds that USF has adequately addressed the required action and additional concern raised in OHRP's August 7, 2003 letter.

As a result of the above determinations, 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. Barry Bercu, USF
Dr. Louis Penner, USF
Mr. Dennis Freeman, USF
Mr. Frank DiPaola, JHVH
Dr. Dimitri Novitzky, USF
Dr. David Weber, Office of Research Oversight, Department of Veterans Affairs
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
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Ms. Yvonne Higgins, OHRP
Ms. Shirley Hicks, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Melinda Hill, OHRP