DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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August 7, 2003

Bruce G. Lindsey, Ph.D.
Interim 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. Lindsey and Mr. Silver:

The Office for Human Research Protections (OHRP) has reviewed the University of South Florida's (USF) April 25, 2002 report in response to OHRP's letter of March 5, 2002 regarding the above-referenced research.

In reviewing the report submitted by USF, OHRP notes the following:

(1) Regarding data collected on Dr. Novitzky's patients, the USF's April 25, 2002 report stated the following:

(a) "The first data set includes patient information and characteristics for all 805 of Dr. Novitzky's patients undergoing CABG [coronary artery bypass grafting] at the VA hospital."

(b) "No patient-identifying information was recorded in the database before July 28, 2000."

(c) "... the USF found that Dr. Novitzky accessed Data Set 1 to compile statistics for general discussion purposes when presenting to his colleagues on the CABG procedure."

(d) "We find Dr. Novitzky's review of the portion of Data Set 1 that contained patient-identifying information to be 'research' requiring IRB [institutional review board] approval and informed consent as defined in 45 CFR 46.102(d). Dr. Novitzky's activity, involving the collection and study of patient medical information, was not exempt from IRB review after July 28, 2000, because following this date the information was collected in such a manner that the subjects could be identified."

(e) "Dr. Novitzky did not obtain IRB approval or legally effective informed consent or seek to waive the requirement of informed consent through the appropriate IRB review process as required by HHS regulations 45 CFR 46.116."

(2) Information collected in Data Set 1 includes private identifiable information collected from July 28, 2000 until April 2, 2002.

(3) A letter dated October 26, 2001 from Dr. Novitzky to John S. Curran, M.D., Vice Dean and Executive Associate Dean for Academic Affairs, USF, which was included with the USF report, states, "As previously indicated, I have conducted no research in the past year and I have fulfilled all the requirements that you set for me on [*sic*] your letter of council [*sic*] dated November 26, 2000."

OHRP notes that in a previous letter dated December 12, 2000 involving another compliance oversight investigation (copy enclosed), USF provided OHRP with the results of an audit of all human subjects research conducted by USF. In that letter, USF identified a number of studies which had not undergone appropriate IRB review and approval. OHRP notes that although Dr. Novitzky had been collecting information as part of Data Set 1 at the time, this was not identified by the USF audit.

Based upon its review of the above referenced materials, OHRP makes the following determinations:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. HHS regulations at 45 CFR 46.102(f) define a human subject as a living individual about whom an investigator conducting research obtains (i) data through intervention or interaction with the individual; or (ii) identifiable private information.

OHRP finds that the activities conducted by Dr. Novitzky involving the collection of data on patients undergoing CABG procedures represented research involving human subjects.

(2) HHS regulations at 45 CFR 46.103(b) and 46.109(a) and the USF MPA and FWA stipulate that the IRB must review and approve all non-exempt human subject research covered by its assurance.

OHRP finds that the research involving collection of data on patients undergoing CABG procedures after July 28, 2000 was not exempt under HHS regulations at 45 CFR 46.101(b) and was initiated without review and approval of the USF IRB.

(3) HHS regulations at 45 CFR 46.116 state that, except as provided elsewhere in the regulations, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subjects or the subject's legally authorized representative. OHRP finds that the investigator initiated human subject research without meeting this requirement.

Corrective Actions: OHRP acknowledges that USF has required (i) the investigator to undergo training and education on human subjects research issues; (ii) the investigator to prepare a presentation on requirements of IRB review of retrospective review and analysis of patient data; (iii) the initiation of a complete audit of the investigator's research activities; and (iv) the investigator to meet quarterly with the Associate Dean for Academic Affairs or the Associate Dean for Research to provide a review of his research compliance.

Required Action: USF must provide OHRP with an updated report on the status of Dr. Novitzky's compliance with the requirements set forth by USF, as well as any additional requirements of the USF IRB. Furthermore, USF must provide OHRP with an update on the status of any projects for which Dr. Novitzky is listed as principal investigator or co-investigator. This update should include any projects that Dr. Novitzky has submitted to the IRB for review along with the actions the IRB may have taken on such projects.

[Redacted]

Please forward your response so that OHRP receives it no later than September 30, 2003.

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

Enclosure: December 12, 2000 USF letter

cc with enclosure:
Dr. Barry Bercu, USF
Dr. Louis Penner, USF
Mr. Dennis Freeman, USF
Mr. Frank DiPaola, JHVH
Dr. Dimitri Novitzky, USF

cc without enclosure:
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
Dr. Kristina Borror, OHRP
Ms. Yvonne Higgins, OHRP
Ms. Shirley Hicks, OHRP
Ms. Melinda Hill, OHRP