



FOR US POSTAL SERVICE DELIVERY:

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

Telephone: 301-435-5654

FAX: 301-402-0527

E-mail: sandy_leikin@nih.gov

August 7, 2000

James N. Cooper, M.D.
Medical Director
Inova Institute of Research and Education
Fairfax Hospital
3300 Gallows Road
Falls Church, VA 22042

RE: Human Subject Protections Under Cooperative Project Assurance
(CPA) # T-3212

Dear Dr. Cooper:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR) has reviewed Inova Institute's July 26, 2000 letter. OHRP has made the following determinations:

- (1) OHRP finds that the Inova Institute's Institutional Review Board (IRB) has reviewed all of the amendments listed in the Clinical Trials Site Visit Report of July 15, 1997.
- (2) OHRP finds that the IRB is now conducting separate deliberations and voting for each protocol undergoing continuing review by the convened IRB.
- (3) OHRP finds that the draft revision of the Inova Institute IRB policies and procedures adequately describe the activities required by HHS regulations at 45 CFR 46.103(b)(4) and
- (5). OHRP notes that final approval of the policies and procedures by the Medical Education and Research Committee is pending.

As a result of the above determinations, and assuming that the above revised policies and procedures as written are approved by the Medical Education and Research Committee, OHRP anticipates no further involvement in the above matters.

August 7, 2000

OPRR 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,



Sanford Leikin, M.D.

Compliance Oversight Coordinator

Division of Human Subject Protections

cc: Dr. Melody Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. J. Thomas Puglisi, OHRP
Mr. George Gasparis, OHRP
Ms. Helen Gordon, OHRP
Ms. Jeanette Tomaszewski, CTEP, NCI
Ms. Jennifer Baldwin, Inova
Ms Gill B. Abernathy, Inova
Dr. Carl Bon Tempo, Inova
Dr. Peter Paganussi, Inova
Dr. Jay Greenberg, Inova
Commissioner, FDA, HF-1
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA