



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: 301-402-5567

FAX: 301-402-2071

E-mail: mc2a@nih.gov

December 15, 2000

Eugene P. Trani, Ph.D.
President
Virginia Commonwealth University
910 West Franklin Street
Box 842512
Richmond, VA 23284-2512

Roy Pickens, Ph.D.
Associate Vice President for Research
Virginia Commonwealth University
Sanger Hall, Room 1-018
1101 East Marshal Street
P.O. Box 980568
Richmond, VA 23298-0568

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1315**

Research Project: Mid-Atlantic Twin Registry (MATR)
Principal Investigator: Linda Corey, Ph.D.

Dear Dr. Trani and Dr. Pickens:

The Office for Human Research Protections (OHRP) has reviewed the following documents provided by Virginia Commonwealth University (VCU):

- (1) VCU's third quarterly progress report dated October 29, 2000, on institutional protections for human subjects at VCU.
- (2) Dr. Picken's December 14, 2000 letter regarding (a) VCU's corrective action plan for ensuring appropriate application of the exemptions stipulated by Department of Health and Human Services regulations at 45 CFR 46.101(b), and (b) modifications that have been made to the MATR research project.

OHRP Findings

Based upon its review of these documents, OHRP makes the following determinations:

(1) OHRP finds that under your leadership VCU has markedly enhanced its system for the protection of human subjects. Among the many enhancements noted by OHRP are the following:

(a) VCU has implemented a multifaceted education program to ensure that all IRB members, all IRB staff, and all research investigators are educated on an ongoing basis about the ethical principles and regulatory requirements for the protection of human subjects.

(b) Since December 1999, VCU has expanded the number of IRBs designated under its MPA from one to three, resulting in a significant reduction in the volume of research protocols reviewed and overseen by each IRB.

(c) VCU has significantly expanded the professional and administrative staff that support the VCU IRBs.

(d) Minutes of VCU IRB meetings now clearly document high-quality, detailed, and substantive reviews of research protocols that reflect the IRBs' understanding of important ethical issues and regulatory requirements related to the protection of human subjects.

(2) OHRP finds that VCU has taken appropriate corrective actions to address all OHRP findings and concerns regarding the MATR research project that were described in OHRP's letters of August 19 and December 17, 1999 letters. In particular, OHRP notes the following modifications to the MATR project that were described in Dr. Picken's December 14, 2000 letter:

(a) The MATR Adult Health Survey instrument will be revised to exclude collection of health information about parents of twin subjects without first obtaining the parents' informed consent.

(b) The MATR Adult Health Survey instrument will be revised to ask each twin if she/he has a family history of each of the medical disorders of interest without specifying the family members who have the disorders.

(c) The MATR Adult Health Survey instrument will be revised to exclude the column requesting health information on "Your Twin." Instead, the respondent will be asked to report on (i) himself/herself, and (ii) other family members with the responses compressed into a single column.

(3) VCU has adequately implemented all required corrective actions stipulated in OHRP's letters of January 11, January 31, June 5, and September 22, 2000.

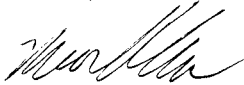
OHRP Action

As a result of the above findings, effective immediately, OHRP has removed the restriction on the VCU Multiple Project Assurance (MPA M-1315), and VCU no longer needs to submit quarterly progress reports to OHRP. Furthermore, OHRP is closing its compliance oversight evaluation of VCU.

Of course, OHRP must be notified should new information be identified which might alter the above determinations.

OHRP appreciates the continued commitment of VCU to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,



Michael A. Carome, M.D.

Director, Division of Compliance Oversight

cc: Dr. William Smith, Chair, IRB-02 (Panel A), VCU
Dr. Deborah L. Haller, Chair, IRB-03 (Panel B), VCU
Dr. Linda Corey, VCU
Dr. Angela Bowen, President, WIRB
Mr. Ron Warren, Senior Vice President, WIRB
Dr. Terry O'Reilly, WIRB
Ms. Marian Linde, FDA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. John Mather, Department of Veterans' Affairs
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. J. Thomas Puglisi, OHRP
Dr. Jeffery Cohen, OHRP
Dr. Clifford C. Scharke, OHRP
Dr. Katherine Duncan, OHRP
Mr. George Gasparis, OHRP
Mr. Barry Bowman, OHRP