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November 30, 2000

Charles K. Francis, M.D.  
President  
Charles R. Drew University of Medicine and Science  
Office of the President  
1731 East 120<sup>th</sup> Street  
Los Angeles, CA 90059

Randall S. Foster, M.H.A.  
Hospital Administrator and Chief Executive Officer  
Martin Luther King Jr./Charles Drew Medical Center  
12021 South Wilmington Avenue, Room 1059  
Los Angeles, CA 90059

**RE: Human Research Subject Protections Under  
Multiple Project Assurance (MPA) M-1386**

Dear Dr. Francis and Mr. Foster:

The Office for Human Research Protections (OHRP) has reviewed your second quarterly progress report dated November 21, 2000, on institutional protections for human subjects at the Charles R. Drew University of Medicine and Science (CRDUMS) and the King/Drew Medical Center (KDMC).

Based upon its review of your progress report, OHRP makes the following determinations:

- (1) OHRP finds that CRDUMS and KDMC have implemented corrective actions which adequately address all concerns relative to systemic protections for human subjects that were identified in OHRP's April 18, 2000 letter.
- (2) OHRP finds that CRDUMS and KDMC have made substantial progress in enhancing their system for protecting human subjects, including (i) implementation of an extensive education program for Institutional Review Board (IRB) members, IRB staff, and investigators; (ii) extensive revision of IRB policies and procedures; (iii) expansion of IRB membership to include additional nonaffiliated and nonscientist members; and (iv) expansion of IRB staff, office space, and resources.

(3) OHRP finds that the minutes of recent IRB meetings clearly documented high-quality, detailed, and substantive reviews of research protocols that reflected the IRB's understanding of important ethical issues and regulatory requirements related to the protection of human subjects.

As a result of the above findings, OHRP is closing its compliance oversight evaluation of CRDUMS and KDMC, and CRDUMS and KDMC no longer need to submit quarterly progress reports to OHRP.

OHRP appreciates your continued commitment to the protection of human subjects. Please feel free to contact me if you have any questions regarding this matter.

Sincerely,



Michael A. Carome, M.D.  
Director, Division of Compliance Oversight

cc: Dr. Harry E. Douglas, Executive Vice President, CRDUMS  
Dr. Kenneth Wolf, Chair, IRB, CRDUMS  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
Dr. Greg Koski, OHRP  
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