

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 301-496-7005
FAX: 301-402-0527

December 23, 2004

Dr. Paul A. Krogstad, M.D.
David Geffen School of Medicine
Department of Pediatrics
Division of Infectious Diseases
10833 Le Conte, Ave., 22-442 MDCC
Mail Code 175217
Los Angeles, California 90095-1752

Subject: Secretary=s Determination under Department of Health and Human Services Regulations at 45 CFR 46.407 on the Research Protocol Entitled AHIV Replication and Thymopoiesis in Adolescents@ (1 R01 AI051996-01A1); Principal Investigator Dr. Paul Krogstad

Dear Dr. Krogstad:

Thank you for your letter of October 20, 2004. On behalf of the Assistant Secretary for Health, Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) finds that all of the stipulations outlined in OHRP=s letter of March 23, 2004 (including the revised requirement under stipulation #11, as agreed to by OHRP and University of California at Los Angeles, required for approval of the above-referenced protocol, have been met.

As a result, OHRP finds that the research conforms with the requirements of HHS regulations at 45 CFR part 46, subpart A, and at 45 CFR 46.407 and 46.408, and now may proceed with the HHS support provided by the National Institute of Allergy and Infectious Diseases under the above-referenced award number.

Page 2 of 2 - Dr. Paul A. Krogstad

Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

/s/ Bernard A. Schwetz

Bernard A. Schwetz, D.V. M., Ph.D. Director
Office for Human Research Protections

cc: Dr. Robert A. Figlin, UCLA

Ms. Judith Brookshire, UCLA

Mr. Steven Peckman, UCLA

Dr. Lana Skirboll, NIH

Dr. Susan Plaeger, NIAID

Dr. Melody Lin, OHRP

Dr. Michael Carome, OHRP

Dr. Irene Stith-Coleman, OHRP

Ms. Elyse Summers, OHRP