adolescents who acquired HIV infection via adult behaviors (sexual contact and illicit drug use), and seronegative adolescents. The proposed research protocol would be funded by the National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIH), under grant number R01 AI 051996.

The specific aims of the study are: (1) To compare quantitative parameters of thymopoiesis and T cell turnover in adolescents and young adults with perinatal HIV infection with those from age-matched individuals with HIV acquired via recent adult behaviors and seronegative control subjects; (2) to evaluate the impact of viral factors on thymopoiesis of HIV infected adolescents; and (3) to examine the cellular immune responses of perinatally-infected adolescents. The long term aims of the study are to better understand the immunological status and prognosis of long-term survivors of perinatal HIV, and to identify possible therapeutic strategies to promote a normal, healthy lifespan for these individuals. The proposed study would enroll a total of 60 to 90 adolescents and young adults (20–30 subjects in each group) and would involve approximately six clinic visits at six month intervals (four visits for control subjects) over a 30-month period, during which medical histories will be obtained and physical exams, blood drawing and CT exams will be performed. At the second visit (six months following initial enrollment), approximately 5–10 subjects from each group (15 to 30 total) will be asked to participate in a substudy of this research protocol. During this substudy, subjects would be admitted to the General Clinical Research Center (GCRC) and be infused intravenously over a 24-hour period with a deuterium-labeled glucose solution, and would have blood drawn at several intervals thereafter. Under the protocol, if the glucose infusion does not permit adequate labeling of immune cells, subjects would receive 70% deuterium-labeled water orally over 24 hours in the GCRC. Subjects would be sent home with additional aliquots 70% deuterium-labeled water to be consumed 2 to 3 times per week for four weeks, and additional blood drawing would be performed during that period.

In July 2002, UCLA forwarded this protocol to the Secretary of HHS for consideration under 45 CFR 46.407, following the determination by the UCLA IRB that the substudy of the proposed research described above could not be approved under 45 CFR 46.404, 46.405, or 46.406, but was suitable for review under 45 CFR 46.407. The IRB found that the substudy was not designed to provide direct benefit to any of the subjects. The IRB also found that the administration of deuterium-labeled glucose in healthy adolescents did not address a disorder or condition in that specific subject population. The IRB found, however, that the proposed research presented a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Experts in relevant disciplines have reviewed this protocol and each have provided recommendations to the Secretary of HHS. In this **Federal Register** Notice, HHS solicits public review and comment pursuant to the requirements of 45 CFR 46.407. The Secretary of HHS will consider the experts' recommendations and the public comments in making a final determination regarding whether or not HHS should support this research.

In particular, comments are solicited on the following questions: (1) What are the types and degrees of risk that this research presents to the subjects; (2) what are the potential benefits, if any, to the subjects and to children in general; (3) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (4) if conducted as proposed in the above-cited protocol, would the research be conducted in accordance with sound ethical principles; and (5) have adequate provisions been made for soliciting the assent of children and the permission of their parents or guardians? In formulating a response to question (4), commenters may wish to consider whether the proposed protocol satisfies all the requirements under HHS regulations at 45 CFR 46.111 (criteria for IRB approval of research).

All written comments concerning this matter should be submitted to Ms. Kelley Booher, Division of Policy, Planning, and Special Projects, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, MD 20852, telephone number (301) 402–5942 (not a toll-free number). Comments also may be sent via facsimile at (301) 402–2071 or by e-mail to: *407panel04@osophs.dhhs.gov.*

Materials to be available for public review on the OHRP Web page (available at: *http://ohrp.osophs.dhhs.gov/panels/407–04pnl/pindex.htm*) will include correspondence from UCLA referring the proposed research protocol to the Secretary of HHS for consideration under 45 CFR 46.407; the original IRB protocol application; correspondence between the UCLA IRB and the principal investigator; relevant excerpts of the NIH grant application, the parental permission and assent documents; and reports from each of experts pursuant to 45 CFR 46.407. A paper copy of the information referenced here is available upon request.

Dated: July 9, 2003.

Arthur J. Lawrence,

Acting Principal Deputy Assistant Secretary for Health.

[FR Doc. 03–17916 Filed 7–15–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Immigration and Nationality Act, Delegation of Authority

Notice is hereby given that I have delegated to the Director, Centers for Disease Control and Prevention, with authority to redelegate, the authorities vested in the Secretary of Health and Human Services under section 412(b)(4) of the Immigration and Nationality Act (8 U.S.C. 1522(b)(4)), as amended hereafter.

This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations.

This delegation is effective upon signature. In addition, I hereby affirm and ratify any action taken by the Director, Centers for Disease Control and Prevention or her subordinates which involve the exercise of the authorities delegated herein prior to the effective date of the delegation

Dated: July 3, 2003.

Tommy G. Thompson,

Secretary.

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