

Board of Governors of the Federal Reserve System, July 10, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03-17932 Filed 7-15-03; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting Notice

Agency Holding the Meeting: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:30 a.m., Monday, July 21, 2003.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT:

Michelle A. Smith, Assistant to the Board; 202-452-2955.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: July 11, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03-18076 Filed 7-11-03; 5:03 pm]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Availability of Funds for Adolescent Family Life Research Grants; Correction

AGENCY: Office of Population Affairs, Office of Public Health and Science, Office of the Secretary, HHS.

ACTION: Notice; correction.

SUMMARY: The Office of Population Affairs published a notice in the **Federal Register** of June 20, 2003 announcing

the availability of funds for adolescent family life research grants. This Notice did not include the RFA (Request for Applications) number. This Notice corrects that error.

FOR FURTHER INFORMATION CONTACT:

Eugenia Eckard, 301-594-4001.

Correction

In the **Federal Register** of June 20, 2003, in FR Doc. 03-15579, beginning on page 36992, an RFA number should have been included. On page 36994, section IV, add the following sentence to the end of the third paragraph: "Reference RFA number HS-03-008".

Dated: July 8, 2003.

Alma L. Golden,

Deputy Assistant Secretary for Population Affairs.

[FR Doc. 03-17917 Filed 7-15-03; 8:45 am]

BILLING CODE 4150-30-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Public Review and Comment on Research Protocol: HIV Replication and Thymopoiesis in Adolescents

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS) is soliciting public review and comment on a proposed research protocol entitled "HIV Replication and Thymopoiesis in Adolescents." The proposed research would be supported by a grant awarded by the National Institute of Allergy and Infectious Diseases, National Institutes of Health. Public review and comment are solicited regarding the proposed research protocol pursuant to the requirements of HHS regulations at 45 CFR 46.407.

DATES: To be considered, written or electronic comments on the proposed research must be received on or before 4:30 p.m. EST September 2, 2003.

ADDRESSES: Submit written comments 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) 402-0527 or by e-mail to: 407panel04@osophs.dhhs.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Leslie K. Ball, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone (301) 496-7005; fax (301) 402-0527; e-mail LBall@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: All studies conducted or supported by HHS which are not otherwise exempt and which propose to involve children as subjects require institutional review board (IRB) review in accordance with the provisions of HHS regulations for the protection of human subjects at 45 CFR part 46, subpart D. Pursuant to HHS regulations at 45 CFR 46.407, if an IRB reviewing a protocol to be conducted or supported by HHS does not believe that the proposed research involving children as subjects meets the requirements of HHS regulations at 45 CFR 46.404, 46.405, or 46.406, the research may proceed only if the following conditions are met: (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (b) the Secretary (HHS), after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, and law) and following opportunity for public review and comment, determines either: (1) That the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406, or (2) that the following conditions are met: (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research will be conducted in accordance with sound ethical principles; and (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408.

HHS received a request from the University of California, Los Angeles (UCLA) pursuant to the provisions of HHS regulations at 45 CFR 46.407. The principal investigator of the above-referenced research protocol, Dr. Paul Krogstad, proposes a longitudinal study evaluating the pathogenic properties of Human Immunodeficiency Virus (HIV), the suppressive and selective power of antiretroviral therapy, and the regenerative capacity of the immune system in adolescents and young adults ages 13 to 24 years with perinatally-acquired HIV infection, compared with two age-matched control groups:

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]

BILLING CODE 4150-36-P

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.

[FR Doc. 03-17918 Filed 7-15-03; 8:45 am]

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