MDUFMA and other expanded programs. GSA will also analyze a range of alternatives for the eastern road access to and through the site including the no action alternative.

As part of the SEIS, GSA will study the impacts of each alternative on the human environment.

Scoping Process

In accordance with NEPA, a scoping process will be conducted to aid in determining the alternatives to be considered and the scope of issues to be addressed, as well as for identifying the significant issues related to the proposed expansion and new road construction to and through the FRC. Scoping will be accomplished through a public scoping meeting, direct mail correspondence to potentially interested persons, agencies, and organizations, and meetings with agencies having an interest in the FRC. It is important that Federal, regional, State, and local agencies, and interested individuals and groups take this opportunity to identify environmental concerns that should be addressed during the preparation of the Draft SEIS.

Public Scoping Meeting

The public scoping meeting will be held on Thursday, June 26, 2003, from 6:30 p.m. to 8:30 p.m. at the CHI Center (Multipurpose Room) located at 10501 New Hampshire Avenue, Silver Spring, Maryland. The meeting will be an informal open house, where visitors may come, receive information, and give comments. GSA will publish notices in the Washington Post and local newspapers announcing this meeting approximately two weeks prior to the meeting. GSA will prepare a scoping report, available to the public, that will summarize the comments received and facilitate their incorporation into the SEIS process.

Written Comments: Agencies and the public are encouraged to provide written comments on the scoping issues in addition to or in lieu of giving their comments at the public scoping meeting. Written comments regarding the environmental analysis for the proposed expansion and construction of a new eastern access road to and through the FRC must be postmarked no later than July 28, 2003, and sent to the following address: General Services Administration, Attention: Harry Debes, Project Executive, 7th and D Streets, SW., Room 2120, Washington, DC 20407. (202) 708–4730 Fax. *Harry.Debes@gsa.gov.*

Dated: June 6, 2003.

Thomas E. James,

Director, Portfolio Management Division.

[FR Doc. 03–15078 Filed 6–12–03; 8:45 am]

BILLING CODE 6820–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National committee on Vital and Health Statistics (NCVHS).

Time and date: June 24, 2003, 9 a.m.–2 p.m.; June 25, 2003, 10 a.m.–12:30 p.m.

Place: Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 705A, Washington, DC 20201.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day the full Committee will hear updates and status reports from the Department on several topics including an update on HHS Data Council activities, the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as on implementation of the HIPAA Privacy Rule. A report on the Consolidated Health Informatics Initiative is also planned. In the afternoon there will be reports from Subcommittees on selected activities. Subcommittee breakout sessions are scheduled for late in the afternoon of the first day and prior to the full Committee meeting on the second day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available. On the second day the Committee will hear presentations on the HHS Gateway to Data and Statistics on the web, and on results of a Gallup Survey on Federal Advisory Committee, followed by reports from Subcommittees. Finally, the agendas for future NCVHS meetings will be discussed.

For Further Information Contact: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Dated: June 6, 2003.

James Scanlon,

Acting Director, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 03–14943 Filed 6–12–03; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Public Review and Comment on Research Protocol: Characterization of Mucus and Mucins in Bronchoalveolar Lavage Fluids From Infants With Cystic Fibrosis

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 ''Characterization of Mucus and Mucins in Bronchoalveolar Lavage Fluids from Infants with Cystic Fibrosis.'' The proposed research would be supported by a grant awarded by the National Heart, Lung, and Blood Institute, 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. July 28, 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 email to: *407panel02@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; email *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, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, 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 North Carolina at Chapel Hill's (UNC) Office of Human Research Studies and Dr. Terry Noah pursuant to the provisions of HHS regulations at 45 CFR 46.407. The proposed research protocol would be funded by the National Heart, Lung, and Blood Institute, National Institutes of Health (NIH), under grant number P50 HL 60280 (SCOR in Pathogenesis of Cystic Fibrosis), principal investigator, Dr. Richard Boucher, and has been adapted from a sub-study contained within this grant, entitled, ''Project IV: Airway Surface Liquid Composition of Humans In Vivo.'' Dr. Terry Noah, the principal investigator of the adapted sub-study, proposes a longitudinal study of the changes in bronchoalveolar lavage fluid (BALF) of infants diagnosed with cystic fibrosis in the neonatal period. The proposed study would enroll infants with a clinical diagnosis of cystic fibrosis in the neonatal period and would obtain BALF from these infants via flexible fiberoptic bronchoscopy at 3 time points: (1) After diagnosis, within the first 6 weeks after birth; (2) at 6 months of age; and (3) at 12 months of age. The goals of the proposed study are to: (a) Quantify mucin in BALF and compare quantities before infection vs. after infection onset in cystic fibrosis; (b) correlate mucin quantity with measures of infection (quantitative bacteriology) and inflammation (cell numbers, neutrophil products, and inflammatory cytokines); and (c) isolate mucus plugs and characterize their histology before and after infection, in order to more accurately describe early relationships among mucus obstruction, infection and inflammation.

After reviewing this research proposal UNC's Committee on the Protection of the Rights of Human Subjects (CPRHS), which serves as UNC's IRB, determined that this research 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 UNC CPRHS found that the research represented more than a minor increase over minimal risk and did not appear to offer the prospect of direct benefit to subjects, but found that the 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. Public review and comment are hereby solicited 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 email to: *407panel02@osophs.dhhs.gov.* Materials available for review on the OHRP web page (available at: *http://ohrp.osophs.dhhs.gov/panels/407–02pnl/pindex.htm*) include: Correspondence from the principal investigator and UNC referring the proposed research protocol to the Secretary of HHS for consideration under 45 CFR 46.407; correspondence between the UNC CPRHS and the principal investigator; the UNC CPRHS deliberations on the proposed research; correspondence between OHRP and UNC; relevant excerpts of the NIH grant application; the parental permission document; review of proposed research by the Cystic Fibrosis Foundation's Data and Safety Monitoring Board; UNC's bronchoscopy complication data; 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: June 5, 2003.

Cristina V. Beato,

Principal Deputy Assistant Secretary for Health.

[FR Doc. 03–14941 Filed 6–12–03; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Public Review and Comment on Research Protocol: Sleep Mechanism in Children: Role of Metabolism

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 ''Sleep Mechanisms in Children: Role of Metabolism.'' The proposed research would be supported by a grant awarded by the National Heart, Lung, and Blood Institute, National Institutes of Health. Public review and comment are