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

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: *407panel03@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 Albert Einstein College of Medicine's Committee on Clinical Investigations (the Albert Einstein CCI, which serves as Albert Einstein's IRB) pursuant to 45 CFR 46.407. The principal investigator, Dr. Gabriel Haddad, proposes to measure glycogen, glutamate turnover rate, and glutamate-glutamine cycling in wakefulness and sleep in adolescent children ages 13 to 17 years. The investigator also proposes to study a subset of children in the same manner following sleep deprivation. The study would involve three visits to the Children's Hospital at Montefiore Medical Center. Measurements will be made using NMR spectroscopy following intravenous infusion of ^{13}C-acetate and ^{13}C-glucose. The long term aims of the study are to better understand (a) sleep; and (b) the diseases afflicting children and adults that impact on their sleep; and (c) sleep-related diseases that impact on neurocognitive, cardiovascular, behavioral, and other functions. This study would be funded by the National Heart, Lung, and Blood Institute, National Institutes of Health (NIH), under grant number HL 070919.

After reviewing this research proposal, the Albert Einstein CCI 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 Albert Einstein CCI found that the research presented more than minimal risk and did not 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 will consider the experts' recommendations and the public comments in making a final determination regarding whether HHS may 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: *407panel03@osophs.dhhs.gov.*

Materials available for review on the OHRP web page (available at: *http://ohrp.osophs.dhhs.gov/panels/407–03pnl/pindex.htm*) include: correspondence from the research institution referring the proposed protocol to the Secretary of HHS for consideration under 45 CFR 46.407; the Albert Einstein CCI protocol application; the Albert Einstein CCI deliberations on the proposed research; the parental permission and assent forms; relevant excerpts of the NIH grant application; and reports from each of the 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.

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BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–76]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on