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.

[FR Doc. 03–14942 Filed 6–12–03; 8:45 am]

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

proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Youth Risk Behavior Survey (YRBS) Methodological Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention, (CDC). CDC intends to conduct a methodological study in the Spring of 2004 to assess the effects of setting and mode of survey administration on the reporting of health-risk behaviors among adolescents, and thereby, to provide methodological guidance for future surveys, especially surveys of adolescents. In 2000, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) commissioned five expert papers written on the topic ''Examining Substance Abuse Data Collection Methodologies.'' The papers focused on the YRBS, the National Survey on Drug Use and Health (NSDUH, formerly the National Household Survey on Drug Abuse, or NHSDA), and Monitoring the Future (MTF). A consensus among the authors was that disparate results across the studies are most likely a product of methodological differences across the surveys. This YRBS Methodological Study is designed to measure the extent to which the prevalence of health-risk behaviors among students varies by whether the survey is administered in schools vs. students' homes (setting), and by whether the survey is administered using paper-and-pencil questionnaire booklets vs. computer-assisted self-interviewing (mode). Approximately 5,376 high school students will be given questionnaires in one of the four setting/mode combinations. Elucidation of the impact of these factors on prevalence will assist in reducing response effects and improving the quality of the YRBS data. There are not costs to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
High school students	5,376	1	45/60	4,032
School administrators	104	1	45/60	78
Total				4,110

Dated: June 9, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–14911 Filed 6–12–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–77]

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 proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

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Proposed Project: Hemophilia Treatment Center Laboratory Survey—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). Up to two million women in the United States may have an inherited bleeding disorder and not know it. Many women learn to live with the problems their bleeding causes, such as heavy periods, and not realize that they could have a bleeding disorder. Other women may have more serious bleeding problems such as hemorrhages after childbirth or surgery, and some have hysterectomies to end their heavy periods. With proper diagnosis, women with bleeding disorders could avoid these complications and surgeries. Management of bleeding in these women can decrease heavy periods and can improve quality of life.

The most common bleeding disorder is called Von Willebrand disease (VWD). VWD is caused by a deficiency or defect in the body's ability to make a protein, von Willebrand factor, which helps blood clot. The symptoms of VWD can range in severity; however, 90 percent of people who have this disease have the mild form. VWD occurs in men and women equally, but women are more likely to notice the symptoms of VWD due to heavy or abnormal bleeding during their menstrual periods and after childbirth. There are many gynecological and physical causes for heavy periods, such as endometriosis, thyroid problems and cancer; however,