encouraging new interested parties to apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include packaging facilities, quality control and pathology/toxicology laboratories, and regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

All travel expenses associated with the site visits will be the responsibility of CBER; therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. A key element of site selection is a successful compliance record with CBER or another agency for which we have a memorandum of understanding. Facilities should also be advised that if a site visit involves a separate physical location of another firm under contract to the applicant, then this contract site must be in agreement to participate in the program, as well as have a satisfactory compliance history.

III. Requests for Participation

Requests are to be identified with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30659 Filed 12–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

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.

Proposed Project: Intervention Trials To Retain HIV-Positive Patients in Medical Care (NEW)

The purpose of this project is to develop, implement, and test the efficacy of an intervention designed to increase client appointment attendance among patients at risk of missing scheduled appointments at HIV clinics. This project is a collaboration between the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and six university-affiliated HIV clinics in the United States. The proposed intervention will be implemented in two phases. Phase 1 is a clinic-wide intervention that includes the following components: a theme slogan for the intervention, brochures, posters with messages to patients, brief verbal retention in care messages from providers to patients, buttons printed with the theme of the intervention worn by providers, and appointment reminder cards with information on how to cancel appointments. All clinic patients will receive the Phase 1 intervention. Phase 2 of the project is a two-arm randomized trial in which 300 patients will be enrolled and randomly assigned to one of two study arms. In Arm 1 (control arm), patients (n=100) will receive the clinic-wide intervention only. Patients (n=200) assigned to Arm 2 (intervention arm) will continue to receive the clinic-wide intervention plus a client-centered intervention from two trained interventionists.

The efficacy of the intervention will be assessed through data collection efforts tailored to each phase of the intervention. Phase 1 uses a pre-post comparison of clinic attendance rates before and during a clinic-wide intervention. Specifically, in Phase 1, the attendance rate for HIV primary care is currently being assessed via electronic medical records during the 12-month period before the clinic-wide intervention begins. This pre-intervention assessment is being collected for all patients who had at least one HIV primary care visit at the clinic during the preceding 12 months. This cohort of patients will be reassessed via electronic medical records during the 12-month intervention period. In addition, provider surveys will be administered quarterly during Phase 1 and semi-annually during Phase 2 to obtain information from primary care providers (MD, DO, nurse practitioner, physician assistant) about whether they talked to their patients about the importance of regular care.

In Phase 2, participants will be enrolled over a period of 4–9-months to allow flexibility for faster or slower enrollment in the clinics. It is anticipated that most clinics will complete their enrollment in approximately 6 months. On a daily basis, clinic staff or the study coordinator will generate a list of patients who meet eligibility criteria based on attendance history. The list will be given to the study coordinator who will approach patients to ask about their interest in being screened for eligibility in the study. When patients agree to be screened for eligibility, the study coordinator will administer an eligibility screener. Patients who are found to be eligible will be enrolled in the project and all enrollees will complete a baseline survey (that will take approximately 30 minutes) before being randomized to the intervention or control arm. No follow-up surveys will be collected. The survey will be

administered in a private setting at the clinic using Audio Computer-Assisted Self-Interview (ACASI) in which respondents can read and listen via earphones to survey questions presented on the computer screen and respond directly into the computer.

Participants randomly assigned into the intervention arm will receive interventional services from two trained interventionists. The intervention will be delivered in face-to-face encounters as well as over the telephone and the first dose of the intervention will be delivered on the day the participant is enrolled into study. During this first face-to-face encounter, an interventionist will administer a retention risk screener. This screener is a clinical tool that will help identify attitudes, barriers, and unmet needs that might prevent a patient from staying in care. The screener contains three sections: (1) Attitudes and beliefs about HIV care and treatment, (2) barriers to consistent clinic attendance (e.g., transportation, child care, housing instability, scheduling problems, and lack of social support), and (3) recent drug/alcohol use and mental health. The information obtained from the risk screener will be used to tailor the intervention to each individual patient's needs. Because a patient's situation or needs may change over time, the screener will be re-administered to intervention arm participants at a minimum every 3–4 months during a clinic visit or other arranged face-to-face meetings outside of the clinic. In addition, the study coordinator will obtain contact/locator information for all participants enrolled in the intervention arm. Contact information will be updated as necessary by the intervention staff.

The response burden for grantees is estimated as:

ESTIMATED ANNUALIZED BURDEN HOURS

Type of form by phase	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden (in hours)
Phase 1 Provider Survey	150	4	600	0.167	100
Phase 2 Provider Survey	150	2	300	0.167	50
Patient Eligibility Screener*	3,000	1	3,000	0.083	249
Patient Baseline Survey*	1,800	1	1,800	0.50	900
Retention Risk Screener	1,200	4	4,800	0.25	1,200
Contact/locator information	1,200	4	4,800	0.083	398
Total Burden	3,150	.....	15,300	.....	2,897

*Only administered one time during the entire project period.

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 18, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–30675 Filed 12–23–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel. Study of Attitudes and Factors Affecting Infant Care.

Date: January 12, 2009.

Time: 11 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver, National Institute for Child Health & Development, 6100 Executive Boulevard, Room 5b01, Bethesda, MD 20812–7510, (301) 435–8382, *hindialm@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 18, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–30728 Filed 12–23–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which