Event	Number of hours/costs per event and labor category* (per respondent)	Approx. number of respondents**	Approx. annual hours (millions)	Approx. total costs (millions)
Total			1.70	31.75

* Staff calculated labor costs by applying appropriate hourly cost figures to burden hours. The hourly rates used were $50 for managerial/professional time (e.g., compliance evaluation and/or planning), $20 for skilled technical time (e.g., designing and producing notices, reviewing and updating information systems), and $10 for clerical time (e.g., reproduction tasks, filing, and, where applicable to the given event, typing or mailing). Consumers have a continuing right to opt-out, as well as a right to revoke their opt-out at any time. When a respondent changes its information sharing practices, consumers are again given the opportunity to opt-out. Again, staff assumes that the time required of consumer to respond affirmatively to respondent's opt-out program (be it manually or electronically) would be minimal.

** The estimate of respondents is based on the following assumptions: (1) 100,000 respondents, approximately 70% of whom maintain customer relationships exceeding one year (2) no more than 1% (1,000) of whom make additional changes to privacy policies at any time other than the occasion of the annual notice; and (3) such changes will occur no more often than once per year.

As calculated above, the average PRA burden for all affected entities in a given year would be 1,000,000 hours and $19,875,000.

Estimated Capital/Other Non-Labor Costs Burden: Staff estimates that the capital or other non-labor costs associated with the document requests are minimal. Covered entities will already be equipped to provide written notices (e.g., computers with word processing programs, typewriters, copying machines, mailing capabilities.) Most likely, only entities that already have on-line capabilities will offer consumers the choice to receive notices via electronic format. As such, these entities will already be equipped with the computer equipment and software necessary to disseminate the required disclosures via electronic means.

William E. Kovacic,

General Counsel.

[FR Doc. 02–12265 Filed 5–15–02; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality; Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

The Health Care Policy and Research Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and quality (AHRQ), and agree to be available, to conduct, or an as needed basis, scientific review or applications for AHRQ support. Individual members of the Panel do not meet regularly and do not serve for fixed terms or long periods of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for Cooperative Agreement Awards are to be reviewed and discussed at this meeting. These discussions are likely to include personal information concerning individuals associated with these applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: Centers for Education and Research on Therapeutic (Limited Competitive Continuation Projects).

Date: June 10, 2002 (Open on June 10, from 8 a.m. to 8:15 a.m. and closed for remainder of the meeting).

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Georgia Room, 3rd Floor, Bethesda, MD 20814.

Contact Person: Anyone wishing to obtain a roster of members or minutes of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Research Review, Education and Policy, AHRQ, 2101 East Jefferson Street, Suite 400, Rockville, Maryland 20852, Telephone (301) 594–1846.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: May 10, 2002.

Carolyn M. Clancy,

Acting Director.

[FR Doc. 02–12310 Filed 5–15–02; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Oak Ridge Reservation Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Oak Ridge Reservation Health Effects Subcommittee (ORRHES).

Time and Date: 12 p.m.–8 p.m., June 18, 2002.

Place: YWCA of Oak Ridge, 1660 Oak Ridge Turnpike, Oak Ridge, Tennessee, 37830. Telephone: (865) 482–2008.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: A Memorandum of Understanding (MOU) signed in October 1990 and renewed in September 2000 between ATSDR and DOE, delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles. In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 2000, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing the public with a vehicle to express concerns and provide advice and recommendations to CDC and ATSDR. The purpose of this meeting is to receive updates from ATSDR and CDC, and to address other issues and topics, as necessary.

Matters to be Discussed: The agenda includes a discussion of the public health assessment, updates from the Public Health Assessment, Health Needs Assessment, Agenda, and Outreach and Communications Workgroups. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: La Freta Dalton, Designated Federal Official, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E–54, Atlanta, Georgia 30333, telephone 1–888–42–ATSDR(28737), fax 404/498–1744.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 9, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–12237 Filed 5–15–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02074]

Interventional Epidemiologic Research Studies to Reduce Mother-to-Child HIV–1 Transmission and Improve Infant Survival in Resource-Limited Countries of High HIV–1 Seroprevalence; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program to support interventional epidemiologic research studies to reduce the burden of HIV/AIDS by preventing mother-to-child HIV–1 transmission peripartum and during breastfeeding in international settings of high HIV–1 seroprevalence. This cooperative agreement will receive cofunding by the National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH) during FY 2003. This program addresses the goals of CDC's HIV Prevention Strategic Plan through 2005.

The purpose of this program is to conduct studies which include clinical trials in resource-limited countries that aim to reduce the risk of perinatal HIV–1 transmission near the time of delivery and during the breastfeeding period among HIV–1 infected women who reside in resource-limited settings and who choose to breastfeed. Also, within the context of these trials, nested research studies will assess mechanisms of transmission during lactation and/or issues related to the effectiveness of, or successful implementation of these interventions.

Background

Worldwide over 600,000 infants each year become HIV–1 infected through mother-to-child transmission. Recent international perinatal trials demonstrated that short course antiretrovirals including zidovudine (AZT), zidovudine/lamivudine (AZT/3TC) and nevirapine (NVP) can reduce the risk of early HIV–1 transmission by about 40 percent in the first 6–14 weeks following delivery. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has recommended that each of these drug regimens can now be considered as possible options for reducing the risk of mother-to-child transmission in resource-limited settings.

However, the global health goal of maximally reducing mother-to-child HIV–1 transmission in resource-limited settings to the low rates (*i.e.,* 5 percent or less) achieved within the U.S. and Europe is yet to be accomplished. Ongoing breast milk transmission results in a near doubling of transmission by 24 months or about 9 percent absolute transmission attributed to breastfeeding between 2–24 months. Two recent studies, a randomized trial of breast milk versus formula in Nairobi and the South African Intrapartum Nevirapine Trial (SAINT) Trial in South Africa compared transmission rates between breastfed and non breastfed infants. Both studies suggest that the first 6–8 weeks may pose the highest risk period of breast milk transmission with about 5–6 percent higher transmission risk for breastfed compared to formula fed infants in the first two months of life. After these first 6–8 weeks, based on observational data from Malawi, ongoing transmission from exposure to breast milk is about 0.6 percent–0.7 percent per month in the first year; and about 0.2–0.3 percent per month in the second year of life.

Currently most HIV–1 infected women in resource-limited settings breastfeed, often into the second year of life. This decision may be related to a number of factors: lack of awareness of their HIV–1 status, cultural norms and strong social reinforcement of breastfeeding, fear or stigma, concerns regarding optimal infant nutrition and also water safety, or cost of breast milk substitutes. Given the high rates of breastfeeding among HIV–1 infected women in resource-limited areas, prevention of HIV–1 transmission during lactation remains a pressing perinatal research challenge.

Examples of Research Areas

I. Clinical Trials Addressing Prevention of HIV–1 Transmission During the Breastfeeding Period

The primary aim of this Program Announcement is to support international clinical trials designed to reduce both peripartum and breastfeeding HIV–1 transmission in rural or urban settings in resource-limited countries.

Critical research areas in preventing mother-to-child HIV–1 transmission that applicants may address, include but are not limited to, clinical trials directed at one of the following areas:

Trials of short course combination antiretrovirals in the last several weeks before delivery designed to reduce viral load to a nondetectable level, followed by maternal or infant antiretroviral prophylaxis during the first several months of lactation;

Trials of short course antenatal or peripartum antiretrovirals paired with infant immune prophylaxis (*e.g.,* HIV–1 vaccine) aimed at protecting the infant throughout the breastfeeding period;

Trials assessing the efficacy of infant combination antiretroviral prophylaxis given to breastfed babies whose mothers were only identified as HIV–1 infected at labor and delivery; and/or

Combinations of above.

II. Nested Research Studies Within Proposed Trials

Investigators should also propose 1–2 nested research questions within the trials addressing mechanisms of transmission during lactation; and/or issues related to effectiveness of, or successful implementation of the intervention. Such studies might include but are not limited to: lab studies addressing mechanisms of transmission during lactation; lab studies assessing the development and waning of drug resistance for antiretrovirals used for perinatal HIV–1 prevention; strategies that enhance uptake of voluntary counseling and testing using rapid HIV testing to support enrollment into the proposed trial; strategies to enhance adherence to antiretrovirals or immune trial interventions antenatally and during lactation; assessment of factors affecting mode of feeding or weaning decisions;