

**Attachment 2c  
Revised 60-Day Notice**

**April 20, 2009**

well as their knowledge, attitudes, and behaviors related to preventive cancer screenings. Of particular interest are adults of various races and ethnicities who are at high risk for lung cancer (i.e., long-term heavy smokers).

The proposed project will use focus groups to gather information about the target audiences' experiences and practices related to lung cancer screening and testing. If warranted from focus group data with adult consumers, follow-up personal interviews will be conducted with selected focus group participants, especially those reporting experience with screening tests, such as spiral computed tomography (CT).

A total of 16 focus groups will be conducted at professional focus group facilities with long-term heavy smokers ages 40–70. The data will be collected from a convenience sample of adults who will be screened and recruited using lists maintained by the focus group facilities. Each focus group will include approximately nine participants and last two hours. If warranted, additional in-depth interviews will be conducted with up to 16 focus group participants.

Eight telephone focus groups will be conducted with a random sample of primary care physicians recruited from the American Medical Association

Physician Masterfile list. Potential physician respondents will be mailed a screening packet to complete and return. Each focus group of physicians will include approximately six participants and last 75 minutes. Two alternates will be recruited for each physician focus group in order to ensure participation of the targeted number of respondents.

Information will be collected over the two-year project period. There are no costs to respondents except their time. The total estimated annualized burden hours are 198.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health Care Consumers .....	Health Care Consumer Screener Form ..	144	1	2/60	5
	Moderator's Guide for Health Care Consumer Focus Groups.	72	1	2	144
	Guide for In-Depth Interviews with Health Care Consumers.	8	1	1	8
Physicians .....	Physician Response Form .....	64	1	5/60	5
	Moderator's Guide for Physician Focus Groups.	24	1	1.5	36
<b>Total .....</b>					<b>198</b>

**Marilyn S. Radke,**  
*Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-80-08BL]

**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 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta,

GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

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. Written comments should be received within 60 days of this notice.

**Proposed Project**

Rapid HIV Testing in Community Mental Health Settings Serving African Americans—New—National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

People with chronic mental illness, including those with substance use disorders, are at increased risk of HIV

compared with the general population. However, not enough is known about the risk behaviors, willingness to be tested for HIV and HIV prevalence among persons with chronic mental illness. In addition, the interrelations among diagnosis of HIV infection, compliance with medical care, subsequent risk behaviors, and the course of mental illness have not been well-described. Mental health clinics are an important setting for HIV rapid testing and promoting prevention efforts against the transmission of HIV infection.

The objectives of this project are to (1) demonstrate improved access to HIV testing and linkage to care in participating mental health care settings; and (2) describe the relationship between mental illness, HIV risk behaviors, and access to testing and services, in order to inform the development of optimal prevention interventions for persons with severe mental illness. Staff at selected implementation sites will offer testing for HIV to clients and administer a brief survey to assess risk behaviors, previous access to similar testing services, and mental health symptoms.

CDC is requesting approval for a 2-year clearance for data collection. Data

will be collected in 6 community mental health sites. This project will collect data from clients using a brief survey administered on a voluntary basis. Collection of data will provide information on client demographics; current behaviors that may facilitate HIV transmission, including sexual and drug-use behaviors; current psychiatric symptoms, determined using brief rating scales; access and barriers to HIV

testing, prevention, and treatment services; and adherence to psychiatric and medical treatment regimens.

CDC estimates the response rate will be approximately 90%. Of the 644 persons approached who agree to be surveyed, it is estimated that 95% of persons will meet the eligibility criteria and 98% will be able to provide informed consent. Therefore, the goal will be to approach 716 persons

annually for participation in the study. The structured interview will take approximately 20 minutes to complete. Participation is voluntary. Data collection will provide important insights into the relationship between HIV/STI risk behaviors and psychiatric illness.

There is no cost to the respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Approached Individual .....	Eligibility Screener .....	644	1	1/60	11
Eligible participant .....	Consent Questionnaire .....	612	1	10/60	102
Consented participant .....	Core Questionnaire .....	600	1	20/60	200
Total .....	.....	.....	.....	.....	313

**Marilyn S. Radke,**  
*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Notice of Public Comment on Tribal Consultation Session To Be Held on September 11, 2008, in Phoenix, AZ**

**AGENCY:** Office of Head Start (OHS).

**ACTION:** Notice of Public Comment on Tribal Consultation Session to be held on September 11, 2008, in Phoenix, Arizona.

**SUMMARY:** Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110-134, notice is hereby given of a one-day Tribal Consultation Session to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal governments operating Head Start (including Early Head Start) programs. The purpose of the Consultation Session is to discuss ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

**Date & Location:** The Consultation Session will be held on September 11, 2008, at the Hyatt Regency Phoenix in Phoenix, Arizona.

**FOR FURTHER INFORMATION CONTACT:** Renée Perthuis, Acting Regional Program Manager, American Indian/Alaska Native Program Branch, Office of Head Start, e-mail [reneeaian@acf.hhs.gov](mailto:reneeaian@acf.hhs.gov) or (202) 260-1721. Register to attend the Consultation Session online at [www.hsnrc.org](http://www.hsnrc.org).

**SUPPLEMENTARY INFORMATION:** The Department of Health and Human Services would like to invite leaders of Tribal governments operating Head Start (including Early Head Start) programs to participate in a formal Consultation Session with OHS leadership. The Consultation Session will take place on Thursday, September 11, 2008, at the Hyatt Regency Phoenix in Phoenix, Arizona.

The purpose of the Consultation Session is to solicit input on ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Specific topics will include policy, research, Head Start/Early Head Start conversion, program quality, and monitoring.

Tribal leaders and designated representatives interested in submitting written testimony or topics for the Consultation Session agenda should contact Renée Perthuis at [reneeaian@acf.hhs.gov](mailto:reneeaian@acf.hhs.gov). The proposal agenda topics should include a brief description of the topic area along with

the name and contact information of the suggested presenter.

The Consultation Session will be conducted with elected or appointed leaders of Tribal governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)]. Representatives from Tribal organizations and Native non-profit organizations are welcome to attend as observers. Those wishing to participate in the discussions must have a copy of a letter signed by an elected or appointed official or their designee, which authorizes them to serve as a representative of the Tribe. This should be submitted not less than three days in advance of the Consultation Session to Renée Perthuis at 202-205-9721 (fax).

A detailed report of the Consultation Session will be prepared and made available within 90 days of the consultation to all Tribal governments receiving funds for Head Start (including Early Head Start) programs.

Dated: July 29, 2008.

**Patricia Brown,**  
*Acting Director, Office of Head Start.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0387]

**Draft Guidance for Industry on Labeling OTC Skin Protectant Drug Products; Availability**

**AGENCY:** Food and Drug Administration, HHS.