

HIV prevention activities and use of funds in HIV prevention nationwide.

CDC HIV prevention program grantees will collect, enter or upload, and report agency-identifying information, budget data, intervention information, and

client demographics and behavioral risk characteristics with an estimate of 207,186 burden hours, an increase from the previously approved, 206,226 burden hours. Data collection will include searching existing data sources,

gathering and maintaining data, document compilation, review of data, and data entry or upload into the web based system.

There are no additional costs to respondents other than their time.

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 Departments | Health Department Reporting | 66 | 2 | 1,435.5 | 189,486 |
| Community-based Organization | Community-Based Organization Reporting. | 150 | 2 | 59 | 17,700 |
| Total | | | | | 207,186 |

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-FY-0840; Docket No. CDC-2018-0036]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Formative Research and Tool Development".

DATES: CDC must receive written comments on or before June 22, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0036 by any of the following methods:

- *Federal eRulemaking Portal:* Regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Formative Research and Tool Development (OMB Control Number 0920-0840, Expiration Date 1/31/2019)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests approval for an approval of a three-year extension to the generic information collection plan titled "Formative Research and Tool Development." CDC designed this information collection project to allow CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) to conduct formative research information collection activities used to inform many aspects of surveillance,

communications, health promotion, and research project development for NCHHSTP's four priority disease prevention focus areas: (1) HIV/AIDS; (2) sexually transmitted diseases/infections (STD/STI); (3) viral hepatitis, tuberculosis elimination (TB); and (4) school and adolescent health (DASH).

Formative research is the basis for developing effective strategies including communication channels, for influencing behavior change. It helps researchers identify and understand the characteristics—interests, behaviors and needs of target populations that influence their decisions and actions.

Formative research is integral in developing programs as well as improving existing and ongoing programs. Formative research also looks at the community in which a public health intervention is being or will be implemented and helps the project staff understand the interests, attributes and needs of different populations and persons in that community. Formative research is research that occurs before a program is designed and implemented, or while a program is being conducted.

NCHHSTP formative research is necessary for developing new programs or adapting programs that deal with the complexity of behaviors, social context, cultural identities, and health care that underlie the epidemiology of HIV/AIDS, viral hepatitis, STDs, and TB in the U.S. as well as for school and adolescent health.

CDC conducts formative research to develop public-sensitive communication messages and user friendly tools prior to developing or recommending interventions, or care. Sometimes these studies are entirely behavioral but most often they are cycles of interviews and focus groups

designed to inform the development of a product.

Products from these formative research studies will be used for prevention of HIV/AIDS, Sexually Transmitted Infections (STI), viral Hepatitis, and Tuberculosis. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC's health communication takes place within campaigns that have fairly lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This information collection approval request will include CDC studies to investigate the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced.

This information collection approval request will also include collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current

needs. CDC will use the information collected to advise programs and provide capacity-building assistance tailored to identified needs.

Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that CDC will cover under this request will include one or more of the following investigational modalities: (1) Structured and qualitative interviewing for surveillance, research, interventions and material development; (2) cognitive interviewing for development of specific data collection instruments; (3) methodological research; (4) usability testing of technology-based instruments and materials; (5) field testing of new methodologies and materials; (6) investigation of mental models for health decision-making, to inform health communication messages; and (7) organizational needs assessments to support development of capacity.

Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements.

In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation of respondents is voluntary.

There is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average hours per response | Total response burden (hours) |
|---|-----------------------------|-----------------------|------------------------------------|----------------------------|-------------------------------|
| General public and health care providers. | Screener | 81,200 | 1 | 10/60 | 13,533 |
| General public and health care providers. | Consent Forms | 40,600 | 1 | 5/60 | 3,383 |
| General public and health care providers. | Individual Interview | 6,600 | 1 | 1 | 6,600 |
| General public and health care providers. | Focus Group Interview | 4,000 | 1 | 2 | 8,000 |
| General public and health care providers. | Survey of Individual | 30,000 | 1 | 30/60 | 15,000 |
| Total | | | | | 46,516 |

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ ATSDR)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR). This meeting is open to the public, limited only by available seating. The meeting room accommodates approximately 60 people. The public is also welcome to listen to the meeting by calling 888–989–4501, passcode 9885805, limited by 100 lines. The deadline for notification of attendance is May 14, 2018. The public comment period is scheduled on June 5, 2018 from 2:30 p.m. until 2:45 p.m., EDT and June 6, 2018 from 10:10 a.m. until 10:25 a.m., EDT. Individuals wishing to make a comment during Public Comment period, please email your name, organization, and phone number by May 7, 2018 to Amanda Malasky at amalasky@cdc.gov.

DATES: The meeting will be held on June 5, 2018, 8:30 a.m. to 4:00 p.m., EDT and June 6, 2018, 8:30 a.m. to 11:30 a.m., EDT.

ADDRESSES: CDC, 4770 Buford Highway, CDC Building 106, Room 1B, Atlanta, GA 30341.

FOR FURTHER INFORMATION CONTACT: Shirley Little, Program Analyst, NCEH/ATSDR, CDC, 4770 Buford Hwy., Mail Stop F–45, Atlanta, GA 30341, telephone (770) 488–0577; email snl7@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC

and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist states and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and wellbeing; and (3) train state and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency's mission to protect and promote people's health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters to be Considered: The agenda will include discussions on Recovery Efforts to Address Environmental Health Impacts after the 2017 Hurricanes, NCEH/ATSDR Program Responses to BSC Guidance and Action Items, PFAS multi-site study, PEASE, Biomonitoring for PFAS in children, Use of Citizen Science for Assessment of Health Risks, Statistical Inferences in Environmental Epidemiology, and NCEH/ATSDR work with tribes/Tribal Programs. Agenda items are subject to change as priorities dictate.

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.

Elizabeth Millington,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1242]

Advisory Committee; Arthritis Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Arthritis Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Arthritis Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until April 5, 2020.

DATES: Authority for the Arthritis Advisory Committee will expire on April 5, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Yinghua Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: AAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Arthritis Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities