

(NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting a three-year Paperwork Reduction Act (PRA) clearance for a Revision to an information collection request (ICR) for a research program focused on identifying the environmental causes of foodborne illness and improving environmental public health practice. This research program is conducted by the Environmental Health Specialists Network (EHS-Net), a collaborative project of the CDC, U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and eight state and local public health programs (California; Tennessee; Minnesota; Rhode Island; New York; New York City, NY; Southern Nevada Health District, NV; and Harris County, TX).

This ICR aims to assess whether an educational intervention will result in

either the development or enhancement of restaurant ill worker policies. This will be accomplished by interviewing restaurant managers, surveying workers, and observing restaurant practices in 320 randomly selected and assigned restaurants in the EHS-Net catchment area. Burden hours would be associated with the restaurant staff for the time to answer questions about their restaurant. There would be two to three site visits depending upon which group the restaurants were assigned to, that is, the intervention or the control group. An initial visit will be used to observe baseline conditions and to provide the intervention only to the restaurants selected to receive it. A second visit will be used to determine if the policies had changed and to introduce the intervention to the control restaurants (if it is deemed successful), and a final follow up visit to the control restaurants that received the intervention on the second visit.

Although approved in 2018, NCEH and its program partners needed to prioritize other data collections over this study, and then had to delay the current study due to the COVID-19 pandemic. NCEH partners provided feedback to refine this research protocol, revise the ICR, and plan to begin this study in 2021. NCEH is requesting approval for revisions which fall into three categories: (1) Changes to comply with the 2018 Revised Common Rule and 21st Century Cures Act; (2) changes to strengthen the study, based on recent experience and stakeholder feedback; and (3) changes to respond to the COVID-19 pandemic.

NCEH is requesting a revised PRA clearance for 715 responses per year and for a time burden of 206 hours per year. These changes result in a decrease of 1,412 responses and 146 hours per year relative to the 2018 PRA clearance. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Restaurant Managers (Intervention Restaurants).	Manager Recruiting Script	119	1	3/60	6
Manager Informed Consent and Interview Form.	53	2	20/60	35	
Restaurant Managers (Control Restaurants).	Manager Recruiting Script	119	1	3/60	6
Manager Informed Consent and Interview Form.	53	3	20/60	53	
Health Department Workers (Intervention Restaurants).	Restaurant Environment Observation Form.	53	2	30/60	53
Health Department Workers (Control Restaurants).	Restaurant Environment Observation Form.	53	2	30/60	53
Total	206

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-1080; Docket No. CDC-2020-0098]

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 HIV Outpatient Study (HOPS). The Centers for Disease Control and Prevention is requesting a three-year extension to the previously approved project to continue collecting standardized HIV clinical and behavioral data at private HIV care practices and university based U.S. clinics participating in the HOPS.

DATES: CDC must receive written comments on or before November 13, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0098 by any of the following methods:

- *Federal eRulemaking Portal:*

Regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; 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

HIV Outpatient Study (HOPS) (OMB Control No. 0920-1080, Exp. 09/30/2021)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention requests a three-year approval for the HIV Outpatient Study data collection activity. The HIV Outpatient Study (HOPS) is a prospective longitudinal cohort of HIV-infected outpatients at eight well established private HIV care practices and university-based U.S. clinics, in Tampa, Florida; Washington, DC; Stony Brook, New York; Chicago, Illinois; Denver, Colorado; and Philadelphia, Pennsylvania. Clinical data are abstracted on an ongoing basis from the medical records of adult HIV-infected HOPS study participants, who also complete an optional telephone/Web-based behavioral assessment as part of their annual clinic visit, which on average takes about seven minutes. Before enrolling in this study, all potential study participants will undergo an informed consent process (including signing of a written informed consent) which is estimated to take 15 minutes.

The core areas of HOPS research extending through the present HIV treatment era include; (i) monitoring death rates and causes of death, (ii) characterizing the optimal patient management strategies to reduce HIV related morbidity and mortality (*e.g.*, effectiveness of antiretroviral therapies and other clinical interventions), (iii) monitoring of sexual and drug use behaviors to inform Prevention with Positives, and (iv) investigating disparities in the HIV care continuum by various demographic factors.

In recent years, the HOPS has been instrumental in bringing attention to emerging issues in chronic HIV infection with actionable opportunities for prevention, including cardiovascular disease, fragility fractures, renal and hepatic disease, and cancers. The HOPS

remains an important source for multiyear trend data concerning conditions and behaviors for which data are not readily available elsewhere, including: rates of opportunistic illnesses, rates of comorbid conditions (*e.g.*, hypertension, obesity, diabetes) and antiretroviral drug resistance.

Data will be collected through medical record abstraction by trained abstractors and by telephone or internet based, computer-assisted interviews at eight funded study sites in six U.S. cities. Collection of data abstracted from patient medical records provides data in five general categories: Demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions (definitive and presumptive); medications prescribed (including dose, duration, and reasons for stopping); all laboratory values, including CD4+ T-lymphocyte (CD4+) cell counts, plasma HIV-RNA determinations, and genotype, phenotype, and trophile results. Data on visit frequency, AIDS, and death are acquired from the clinic chart. Data collected using a brief Telephone Audio-Computer Assisted Self-Interview (T-ACASI) survey or an identical Web-based Audio-Computer Assisted Self-Interview (ACASI) include: Age, sex at birth, use of alcohol and drugs, cigarette smoking, adherence to antiretroviral medications, types of sexual intercourse, condom use, and disclosure of HIV status to partners.

We anticipate that 450 new HOPS study participants will be recruited annually into the HOPS from a pool of HIV-infected individuals currently in HIV-care at the nine aforementioned clinics (50 patients per site). Patients are approached during one of their routine clinic visits to participate in the HOPS. Patients interested in participating in the HOPS are given detailed information about the nature of the study and provided with written informed consent that must be completed prior to enrollment. The 450 newly enrolled participants each year will be added to the database of existing participants such that approximately 2,500 participants will be seen in the HOPS each year. Medical record abstractions will be completed on all HOPS participants and impose no direct burden on HOPS study participants. Participation of respondents is voluntary. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
HOPS study Patients	Behavioral survey	2,500	1	7/60	292
HOPS Study Patients	Consent form	450	1	15/60	113
Total	405			

Jeffrey M. Zirger,
*Lead, Information Collection Review Office,
 Office of Scientific Integrity, Office of Science,
 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, Center for Preparedness and Response

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, Center for Preparedness and Response, (BSC, CPR). This is a virtual meeting that is open to the public, limited only by the number of net conference access available, which is 500. Pre-registration is required by accessing the link at https://cdc.zoomgov.com/webinar/register/WN_bV_Jrvp4QZGHZFao0moqPg.

DATES: The meeting will be held on October 26, 2020, from 12:30 p.m. to 3:30 p.m., EDT.

ADDRESSES: Zoom Virtual Meeting. If you wish to attend the virtual meeting, please pre-register by accessing the link at https://cdc.zoomgov.com/webinar/register/WN_bV_Jrvp4QZGHZFao0moqPg.

Instructions to access the Zoom virtual meeting will be provided in the link following registration.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop-H21-6, Atlanta, Georgia 30329-4027, Telephone: (404) 639-7450; Facsimile: (404) 471-8772; Email: OPHPR.BSC.Questions@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Center for Preparedness and Response (CPR), concerning strategies and goals for the programs and research within CPR, monitoring the overall strategic direction and focus of the CPR Divisions and Offices, and administration and oversight of peer review for CPR scientific programs. For additional information about the Board, please visit: <https://www.cdc.gov/cpr/bsc/index.htm>.

Matters To Be Considered: The agenda will include discussions on updates from the CPR Director and Division Directors, CPR Strategic Planning and Science Agenda, and CPR BSC Polio Containment Workgroup (PCWG) Updates. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, 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.

Kalwant Smagh,

*Director, Strategic Business Initiatives Unit,
 Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

A National Elastomeric Half Mask Respirator (EHMR) Strategy for Use in Healthcare Settings During an Infectious Disease Outbreak/Pandemic

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces this request for information regarding the deployment and use of elastomeric half-mask respirators in healthcare settings and emergency medical services (EMS) organizations during the COVID-19 crisis.

DATES: Comments must be received October 14, 2020.

ADDRESSES: Responses should be submitted to Dr. Lee Greenawald, NIOSH, 626 Cochran Mill Road, Building 141, Pittsburgh, PA 15236, or ppeconcerns@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Lee Greenawald, NIOSH, 626 Cochran Mill Road, Building 141, Pittsburgh, PA 15236; phone: (412) 386-6465 (not a toll-free number, email: ppeconcerns@cdc.gov).

SUPPLEMENTARY INFORMATION:

Public Participation

Informational submissions in response to this request for information (RFI) are due no later than October 14, 2020. Please limit informational submissions for each of the two sections to five pages or less (for a total of 10 pages or less).

NIOSH will not respond to individual informational submissions or publish