

because the majority of new HIV infections occur each year among this population. In each year of the study, an average of 1,667 participants will be recruited from the Public Health—Seattle and King County (PHSKC) STD Clinic, which serves as the primary study site, and an additional 200 persons will be enrolled from other clinics in the greater Seattle area. Information collection will be conducted in two phases.

Phase 1: After a clinic client consents to participate, he/she will be assigned a unique participant ID and will then undergo testing with the seven new HIV tests under study. While awaiting test results, participants will undergo additional specimen collections and complete the Phase 1 Enrollment Survey.

Phase 2: All Phase 1 participants whose results on the seven tests under investigation are not in agreement with one another (“discordant”) will be considered to have a potential early HIV infection. Nucleic amplification testing that detects viral nucleic acids will be conducted to confirm an HIV diagnosis and rule out false positives. Study investigators expect that each year, 50 participants with discordant test results will be invited to participate in serial follow-up specimen collections to assess the time point at which all HIV test results resolve and become concordant positive (indicating enrollment during

early infection) or concordant negative (indicating one or more false-positive test results in Phase 1).

The follow-up schedule will consist of up to nine visits scheduled at regular intervals over a 70-day period. At each follow-up visit, participants will be tested with the new HIV tests and additional oral fluid and blood specimens will also be collected for storage and use in future HIV test evaluations at CDC. Participants will be followed up only to the point at which all their test results become concordant. At each time point, participants will be asked to complete the Phase 2 HIV Symptom and Care survey that collects information on symptoms associated with early HIV infection, as well as access to HIV care and treatment since the last Phase 2 visit. When all tests become concordant (*i.e.*, at the last Phase 2 visit) participants will complete the Phase 2 behavioral survey to identify any behavioral changes during follow-up. Of the 50 Phase 2 participants, it is estimated that no more than 26, annually, will have early HIV infection.

All data for the proposed information collection will be collected via an electronic Computer Assisted Self-Interview (CASI) survey. Participants will complete the surveys on an encrypted computer, with the exception of the Phase 2 Symptom and Care survey, which will be administered by

a research assistant and then electronically entered into the CASI system. Data to be collected via CASI include questions on sociodemographic characteristics, medical care, HIV testing, pre-exposure prophylaxis, antiretroviral treatment, sexually transmitted diseases (STD) history, symptoms of early HIV infection, substance use and sexual behavior. Data from the surveys will be merged with HIV test results and relevant clinical data using the unique identification (ID) number.

CDC will use findings to update guidelines for HIV testing and diagnosis in the United States. The guidelines will help HIV test providers choose which HIV tests to use, and target tests appropriately to persons at different levels of risk. Findings will also be disseminated through articles in peer-reviewed journals and the technical assistance provided by CDC to grantees that provide HIV testing and diagnostic services.

There are no changes to the previously approved information collection instruments or burden estimates. The participation of respondents is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden for the proposed project is 2,110 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Persons eligible for study	Phase 1 Consent	2,334	1	15/60
Enrolled participants	Phase 1 Enrollment Survey A	1,667	1	45/60
	Phase 1 Enrollment Survey B	200	1	60/60
	Phase 2 Consent	50	1	15/60
	Phase 2 HIV Symptom and Care survey	50	9	5/60
	Phase 2 Behavioral Survey	50	1	30/60

Jeffrey M. Zirger,

Acting 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-19-0017; Docket No. CDC-2018-0109]

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 *Application for Training* (OMB Control No. 0920-0017). The Training and Continuing Education Online (TCEO) system is used in the management of the accreditation

process for non-federal educators who develop public health and healthcare educational activities and for non-federal health professionals who seek continuing education necessary to maintain professional licensures and certifications. This request for revision is to add new questions to the TCEO New Participant Registration, a new TCEO Post-Course Evaluation, and a new TCEO Follow-up Evaluation. Both new evaluation tools will improve the quality of educational activities. Each TCEO tool ensures compliance with accreditation requirements.

DATES: CDC must receive written comments on or before February 8, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0109 by any of the following methods:

- *Federal eRulemaking Portal:* *Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Acting Lead, 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: 404-639-7570; 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

Application for Training (OMB Control No. 0920-0017, Exp 06/30/2019)—Revision—Division of Scientific Education and Professional Development (DSEPD), Center for Surveillance, Epidemiology and Laboratory Services (CELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

DSEPD requests a three-year Revision to the Training and Continuing Education Online (TCEO) system, which will comprise four data collection and management tools. Requested revisions are (1) to add questions to the existing TCEO New Participant Registration and (2) to introduce a Post-Course Evaluation and a Follow-Up Evaluation. No changes are requested for the existing TCEO Proposal Tool.

TCEO provides access to CDC educational activities that offer continuing education to public health and healthcare professionals (learners) to maintain their professional licensures and certifications. Licensures and certifications are mandatory for certain health professionals to provide services that prevent and mitigate illness and save lives. Employees of hospitals, universities, medical centers, state and local health departments, and federal agencies participate in CDC's accredited educational activities to learn about current public health and healthcare practices. CDC is accredited by seven accreditation organizations to provide continuing education for public health and healthcare professionals.

CDC and CDC-funded educational activities include classroom study, conferences, and electronic learning (e-learning). The TCEO Proposal expedites submission, review, and accreditation processes for these CDC and CDC-funded educational activities. The information collected from educational developers provides CDC with the information necessary to meet accreditation requirements. CDC reviews proposals to ensure compliance with requirements and awards continuing education when activities meet accreditation standards. The educational activities that can offer continuing education are then added to TCEO for learners to access.

Accreditation organizations require a method of tracking learners who complete an educational activity and some require collection of profession-specific data, among other requirements. CDC requires health professionals who seek continuing education to establish an account by completing the TCEO New Participant Registration. CDC relies on this electronic form to collect information needed to coordinate learner registrations for educational activities.

The proposed inclusion of two new evaluation tools is required by accreditation organizations to ensure compliance with accreditation standards. Public health professionals will be required to take the TCEO Post-course Evaluation after they have participated in an educational activity and before they can earn continuing education. Health professionals who have received continuing education for the activity will be encouraged to complete the TCEO Follow-up Evaluation when a link is sent to them from TCEO by email. Reports on responses to both tools will be submitted to accreditation organizations when they conduct audits or when CDC requests renewal of accreditation. Both new tools provide information to help CDC improve the quality of its educational activities.

Proposed changes not only ensure that CDC is in compliance with accreditation requirements, changes will improve the quality of educational activities, while continuing to offer accredited educational activities at no cost to learners. Because of the increasing demand for accredited educational activities that offer free CE for licensures and certifications, TCEO experiences a continued increase in educational activities completed each year by registered learners. Every year, the number of times learners complete steps to earn continuing education increases by approximately 15%. The

two new evaluation tools will be shared with all learners who complete educational activities in TCEO, causing the annual burden estimate to increase significantly. The annual burden table

has been updated to reflect the new TCEO Post-course Evaluation (66,667 burden hours) and the new TCEO Follow-up Evaluation (2,000 burden hours), for a total of 85,934 burden

hours that include all four TCEO tools. There are no 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)
Educational Developers (Health Educators).	TCEO Proposal	120	1	5	600
Public Health and Health Care Professionals (Learners).	TCEO New Participant Registration	200,000	1	5/60	16,667
Public Health and Health Care Professionals (Learners).	TCEO Post-course Evaluation	200,000	2	10/60	66,667
Public Health and Health Care Professionals (Learners).	TCEO Follow-up Evaluation	20,000	2	3/60	2,000
Total	420,120	85,934

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-18PR]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The World Trade Center Health Program (WTCHP): Impact Assessment and Strategic Planning for Translational Research (Part 1, Formative Research: Focus Groups) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 15, 2018 to obtain comments from the public and affected agencies. The WTCHP is administered by the CDC/ National Institute for Occupational Safety and Health (NIOSH). CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget

is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The World Trade Center Health Program: Impact Assessment and Strategic Planning for Translational Research (Part 1, Formative Research:

Focus Groups)—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The World Trade Center Health Program (WTCHP) was established by the James Zadroga 9/11 Health and Compensation Act of 2010, Public Law 111-347 (hereafter referred to as "the Zadroga Act"). Under subtitle C, the Zadroga Act requires the establishment of a research program on health conditions resulting from the 9/11 terrorist attacks. The Research to Care (RTC) model is the strategic framework employed by the WTCHP to prioritize, conduct, and assess research that informs excellence in clinical care for the population of responders and survivors affected by the 9/11 attacks in New York City. It is the focus of this assessment.

The RTC model assumes the collective involvement of different WTCHP stakeholders, including members, researchers, clinicians, and program administrators. It accounts for a variety of inputs that can affect the progress and impact of WTCHP research. These inputs include people and organizations (e.g., program members, providers, clinical centers of excellence, extramural researchers, and program staff), resources (e.g., technology, data centers, the NYC 9/11 Health Registry) and regulatory rules, principally the Zadroga Act. The program supports activities such as research prioritization, conduct of research, delivery of medical care, and iterative assessments of the translation of research to improvements in health care services and chronic disease