Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-17CA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Positive Health Check Evaluation Trial - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

HIV transmission continues to be an urgent public health challenge in the United States. According to the Centers for Disease Control and Prevention (CDC), approximately 1.2 million

people are living with HIV, with close to 50,000 new cases each year. Antiretroviral therapy (ART) suppresses the plasma HIV viral load (VL) and people living with HIV (PLWH) who are treated with ART—compared with those who are not—have enhanced clinical outcomes and a substantially reduced risk of transmitting HIV sexually, through drug sharing, or from mother to child. However, it is estimated that only 30% of people who are infected with HIV in the United States have an undetectable HIV VL. To enhance HIV prevention efforts, implementable, effective, scalable interventions are needed that focus on enhancing prevention and care to improve the health of and reduce HIV transmission risk among PLWH. The Positive Health Check (PHC) intervention is based on earlier computer-based interventions that were proven efficacious for HIV prevention.

The PHC intervention approach is innovative in multiple ways. First, it uses an interactive video doctor to deliver tailored messages that meet specific patient needs related to ART initiation, adherence, sexual risk reduction, engagement in care, mother-to-child transmission, and drug use. Second, this intervention is designed specifically to support improved health outcomes by providing useful behavior-change tips for patients to practice between clinic visits. These tips are generated by the tool and selected by the patient and populated on a handout that is delivered to the patient upon completing the PHC

intervention. The handout has no patient-identifying information. Third, PHC supports patient-provider communication by also generating a set of questions that patients may select to ask their provider. These PHC behavior-change tips and questions are populated on a Patient Handout to guide patients' conversations with their providers and if desired, patients may choose to share their handout with their provider. As such, PHC supports the interactions between patients and their providers during their clinical encounter and is intended to improve communication. Finally, the PHC intervention has been designed from the onset for wide-scale dissemination. This web-based intervention can be easily updated and is accessible on multiple mobile devices and platforms. This approach makes PHC an important intervention strategy to improve public health in communities that have a high incidence of HIV infection.

The PHC Evaluation Trial has four primary aims: 1.) Implement a randomized trial to test the effectiveness of the PHC intervention for improving clinical health outcomes, specifically viral load and retention in care; 2.)Conduct a feasibility assessment to determine strategies to facilitate implementation and integration of PHC into the workflow of HIV primary care clinics; 3.) Collect and document data on the cost of PHC intervention implementation; and 4.) Document the standard of care at each participating clinic. The awardee of

this cooperative agreement—Research Triangle International (RTI)—has subcontracted with four clinical sites to implement the trial (Atlanta VA Medical Center (Atlanta, GA), Hillsborough County Health Department (Tampa, FL), Rutgers Infectious Disease Clinic (Newark, NJ) and Crescent Care (New Orleans, LA). The four clinical sites) are well suited for this work, given the high rates of patients with elevated viral loads.

During the 36-month study period, 1,010 patients will be enrolled into the trial (505 intervention arm and 505 control arm) across the four clinics to evaluate the effectiveness of the PHC intervention. Upon enrollment, participants will be asked their date of diagnosis. To assess the effectiveness of the PHC intervention (Aim 1), patients randomized to the intervention arm will provide their responses to the patient tailoring questions embedded within the intervention and all enrolled patients will consent to have their de-identified clinical values be made available via passive data collection via the electronic medical record (EMR). In addition to the main trial, three to five key staff at each clinic site will be selected to participate in the PHC feasibility assessment (Aim 2) which includes an online survey and qualitative interviews. Clinic staff will provide data on the cost of implementing the PHC intervention (Aim 3). Finally, the medical director of each

clinic will collect data on their clinic's standard of care (Aim 4).

OMB approval is requested for three years. Participation in this study is voluntary. The total estimated annualized burden hours are 419.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in Hours)
Patients Enrolled in the PHC Evaluation Trial	Date of diagnosis question	337	1	1/60
	PHC tailoring questions	168	3	5/60
Staff in PHC Evaluation Clinics	Electronic Medical Record (EMR)	4	4	16
	Online clinic staff survey	20	4	15/60
	Clinic staff qualitative interview	20	4	40/60
	Non-research labor cost questionnaire	4	1	1.5
	PHC labor cost questionnaire	4	1	1.5
	Standard of Care Questionnaire	4	1	1.5
	PHC non-labor cost questionnaire	4	12	30/60

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[FR Doc. 2017-13735 Filed: 6/29/2017 8:45 am; Publication Date: 6/30/2017]