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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16CM]

[Docket No. CDC-2015-0097]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. CDC is requesting a new three-year approval for "The Cooperative Re-engagement Controlled Trial (CoRECT)" information collections.

DATES: Written comments must be received on or before [**INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0097 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions*:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted 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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

The Cooperative Re-engagement Controlled Trial (CoRECT) - New - 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 (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a new three-year OMB approval for information collection for a new research study entitled "The Cooperative Re-engagement Controlled Trial (CoRECT)". The purpose of the study is to evaluate a combined health department and clinic intervention to improve engagement in HIV care. Increasing the number of people living with HIV who access HIV care and achieve viral load suppression addresses one of the priorities of the National HIV/AIDS Strategy.

The CoRECT Study data collection is comprised of six core components: 1. electronic clinic data abstraction (Electronic Medical Record (EMR) abstraction will be conducted by project clinic staff at each project clinic to develop the clinic-based "Out of Care" list; 2. electronic surveillance data abstraction (Electronic surveillance data abstraction will be conducted by project health department staff at each health department to develop the health department based "Out of Care" list); 3. a "Barriers to Care" survey (These surveys will provide

information regarding barriers to accessing healthcare (e.g., transportation, financial assistance, housing, substance abuse services, etc.); 4. “Standard of Care” survey (Investigators will administer this survey to clinic managers, at baseline and every six months during the study period to assess how the delivery of health services has evolved over time) 5. Preliminary Case Investigations form (a listing of potential out-of-care patients will be reviewed to determine those who appear to be out-of-care, as determined by study eligibility, versus those who meet criteria for exclusion); and 6) Case Conference form (project health department staff will determine if potentially eligible patients met criteria for inclusion in the study and if so randomization will occur).

Prospective data collection will provide information about participant’s baseline characteristics including sex, race/ethnicity, HIV exposure risk category, CD4 and viral load test results, date of first clinic visit, and insurance status.

HIV antiretroviral therapy (ART) can durably suppress the plasma HIV viral load, which improves individual survival and dramatically reduces further HIV transmission. Increasing the number of people living with HIV who access HIV care and achieve viral load suppression is a priority of the National HIV/AIDS

Strategy. Within the continuum of HIV care in the United States, improvements in linkage to and retention in effective care provide the greatest opportunity to improve rates of HIV viral suppression. It is estimated that of the 1.2 million persons living with HIV in 2011, only 40% were engaged in HIV medical care and only 30% achieved viral suppression.

HIV clinical trials with enhanced case management have demonstrated that interventions provided by the health department can improve linkage to HIV care and interventions provided by the clinic can improve retention in HIV care. Although linkage to care has improved in many health department jurisdictions, being linked to care is not enough. There is a need to ensure that: (i) people diagnosed with HIV and linked to care are engaging medical care (i.e., attending their enrollment appointment and returning for follow-up medical appointments); and (ii) people who have disengaged from HIV care (i.e., have missed medical appointments and have not been seen in clinic for more than 6 months) are able to efficiently re-engage in care. There have been no randomized controlled studies using a Data-to-Care approach to identify and re-engage out of care persons. Controlled studies such as the CoRECT study are critical to determine the effectiveness of HIV prevention interventions.

The CoRECT study is a randomized controlled trial that seeks to establish a data-sharing partnership between health departments and HIV care clinical providers to identify HIV-infected persons who are out of care and evaluate an intervention that aims to have randomized participants: (a) link to an HIV clinic; (b) remain in HIV medical care; (c) achieve HIV viral load suppression within 12 months; and (d) achieve durable HIV viral load suppression over 18 months.

The study is funded by CDC through cooperative agreements with the Connecticut State Department of Public Health (in collaboration with Yale University School of Medicine), the Massachusetts State Department of Public Health, and the Philadelphia Department of Public Health.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Study Coordinator	Electronic transmittal of surveillance variables	3	4	1	12
Clinic data manager	Electronic transmittal of clinical variables	46	4	1	184
CoRECT study Participants	Barriers to Care Survey	1,200	1	30/60	600
Clinical Nurse Coordinator	Standard of Care Survey	46	2	45/60	69
Clinic data manager	Case Conference Session	46	12	1	552
CoRECT study Coordinator (health department)	Case Conference Session	3	12	1	36
CoRECT study Coordinator (health department)	Preliminary Case Investigation	3	12	1	36
Clinic Data Manager	Preliminary Case Investigation	3	12	1	36
Total					1,525

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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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