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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-FY-15BBV]

[Docket No. CDC-2015-0066]

**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. This notice invites comment on a proposed information collection

entitled "Screening and Counseling of Male EVD Survivors to Reduce Risk of Sexually Transmitting Ebola Virus in Guinea". This activity will collect information on participants' laboratory results and sexual activity prior to and during participation in the screening program.

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-2015-0066 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.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](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.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 Projects

Screening and Counseling of Male EVD Survivors to reduce Risk of Sexually Transmitting Ebola Virus in Guinea - New - Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Much progress has been made in the year since the CDC first responded to the Ebola outbreak in West Africa, but the agency's efforts must continue until there are zero new cases of Ebola virus disease (EVD). In order to reach the international goal of zero new EVD cases in 2015, the agency must intensify its efforts to identify and prevent every potential route of human disease transmission and to understand the most current community barriers to reaching that final goal.

"Screening and Counseling of Male EVD Survivors to reduce Risk of Sexually Transmitting Ebola Virus in Guinea" will inform male Ebola infection survivors ≥ 15 years of age of Ebola virus detected in their semen through voluntary laboratory testing performed in Guinea. Participants for the semen testing program will be recruited by trained study staff from Ebola treatment units (ETUs) and survivor registries in Guinea. Participants will be followed up at study sites in government hospitals.

Specimens will be tested for Ebola Virus ribonucleic acid

(RNA) by reverse transcription polymerase chain reaction test (RT-PCR). Semen specimens will be collected and tested every two weeks until two consecutive negative RT-PCR results are obtained.

Participants will be asked follow-up questions until their semen specimens test negative twice consecutively. They will receive tokens of appreciation for their participation at the initial visit and again at every subsequent follow-up visit and a supply of condoms.

A trained study data manager will collect test results for all participants in a laboratory results form. Results and analyses are needed to update relevant counseling messages and recommendations from the Guinea Ministry of Health, World Health Organization, and CDC.

This program will provide the information that is critical to the development of public health measures, such as recommendations about sexual activity and approaches to evaluation of survivors to determine whether they can safely resume sexual activity. These approaches in turn are expected to reduce the risk of Ebola resurgence and mitigate stigma for thousands of survivors. The information is likewise critical to reducing the risk that Ebola would be introduced in a location that has not previously been affected.

CGH requests a three-year approval for this information

collection. Each semen-testing program time burden is 2,067 hours which is incurred by 1,000 participants. There are no other costs to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Male Ebola Survivors ≥15 years old	Baseline Questionnaire	1,000	1	20/60	334
Male Ebola Survivors ≥15 years old	Follow-up Questionnaire	1,000	8	10/60	1,334
Male Ebola Survivors ≥15 years old	Consent Form	1,000	1	2/60	34
Total					1,702

Leroy A. Richardson
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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

[FR Doc. 2015-20812 Filed: 8/21/2015 08:45 am; Publication Date: 8/24/2015]