Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-15BFV]

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

A Study of Viral Persistence in Ebola Virus Disease (EVD) Survivors – Existing Information Collection Without an OMB Control Number – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), 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). As the CDC's 2014 Ebola virus response maintains 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.

Persistence of Ebola Virus (EBOV) in Body Fluids of EVD Survivors in Sierra Leone is the first systematic examination of the post-recovery persistence of EBOV and the risks of transmission from a cohort of convalescent Ebola survivors during close or intimate contact. It is important to fully understand how long the virus stays active in body fluids other than blood in order to target and refine public health interventions to arrest the ongoing spread of disease.

The research study is comprised of three modules based on the body fluids to be studied: A pilot module of adult males (semen) and two full modules: Module A of adult men and women repeating collections and questionnaires every two weeks (semen, vaginal secretions, and saliva, tears, sweat, urine, rectal swab), and Module B of lactating adult women repeating

collections and questionnaires every three days (sweat and breast milk).

Participants for each module will be recruited by trained study staff from Ebola treatment units (ETUs) and survivor registries. Participants will be followed up at study sites in government hospitals.

Specimens will be tested for EBOV ribonucleic acid (RNA) by reverse transcription polymerase chain reaction test (RT-PCR) in Sierra Leone at the CDC laboratory facility in Bo. All positive RT-PCR samples will be sent to CDC Atlanta for virus isolation. Each body fluid will be collected until two negative RT-PCR results are obtained. Participants will be followed until all their studied body fluids are negative. They will receive tokens of appreciation for their participation at the initial visit and again at every subsequent follow-up visit [e.g., 120,000 Leones (approximately $28 US dollars) and a supply of condoms]. For Module A, men and women will be recruited in equal numbers for this study until more information on gender effects of viral persistence is available. 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 Sierra Leone Ministry of Health, World Health Organization, and CDC. The

study will provide the most current information that is critical to the development of public health measures, such as recommendations about sexual activity, breastfeeding, and other routine activities 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.

The total burden hours requested for the research study in Sierra Leone is 1,836 hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)
Data manager	Intake Form	1	550	20/60
Pilot participants	Survivor Questionnaire	100	1	30/60
Pilot participants	Survivor Follow-up Questionnaire	100	5	15/60
Pilot participants	3 & 6 Month Follow up Questionnaire	100	2	15/60
Main study male	Survivor Questionnaire	120	1	30/60

participants				
Main study male participants	Survivor Follow-up Questionnaire	120	12	15/60
Main study male participants	3 & 6 Month Follow Questionnaire	120	2	15/60
Main study female participants	Survivor Questionnaire	120	1	30/60
Main study female participants	Survivor Follow-up Questionnaire	120	4	15/60
Main study female participants	3 & 6 Month Follow up Questionnaire	120	2	15/60
Data manager	Laboratory Results Form	1	4,250	10/60

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Office of Scientific Integrity,
Office of the Associate Director for Science,
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Centers for Disease Control and Prevention.

[FR Doc. 2016-07803 Filed: 4/4/2016 8:45 am; Publication Date: 4/5/2016]