

Centers for Disease Control and Prevention (CDC) Atlanta GA 30333

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Subject: Request for OMB Paperwork Reduction Act Emergency Review

To: Cortney Higgins, PhD

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Through: Leroy Richardson, MS, MPH, MSCJ, CPHA

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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. Pursuant to the Office of Management and Budget (OMB) procedures established under 5 CFR 1320, Controlling Paperwork Burdens on the Public, the CDC requests that the collection of information, "Persistence of Ebola Virus in Body Fluids of Ebola Virus Disease Survivors in Sierra Leone," be processed in accordance with Section 1320.13 Emergency Processing. The CDC cannot reasonably comply with the normal clearance procedures under the PRA because the window to conduct this research is quickly closing, and failure to conduct the research will leave important questions about virus transmission unanswered. Identifying alternative transmission routes, however low the probability may be, could be the key to preventing a resurgence of the epidemic. Thus the goal of zero new cases is essential for the CDC to fulfill its public health mission to end the Ebola outbreak as quickly and as completely as possible.

It is important to elucidate the post-recovery persistence of Ebola virus (EBOV) in body fluids over time and the risks of transmission from convalescent Ebola survivors during close or intimate contact. Previous studies suggest limited persistence of virus in most body fluids (sweat, saliva, urine, feces, breast milk, and vaginal secretions). However, live Ebola virus has been shown to persist in semen for up to 82 days after onset of first Ebola symptoms, while Ebola virus ribonucleic acid (RNA) has been detected in semen of survivors up to 120 days after onset. Recent cases of Ebola in female patients that were linked to sexual intercourse with a male survivor have been investigated in all three heavily-affected countries (Sierra Leone, Liberia, and Guinea).

As a result of these previous findings, the general recommendation has currently been for male and female survivors to abstain from sexual activity for at least three months after recovery from Ebola, or to use condoms if abstinence is not possible. Similarly breastfeeding is not recommended if the survivor has an infant that was not an Ebola case. The study will provide 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 CDC requests that OMB approval is obtained by May 20, 2015 so that the information collection can begin.

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