Non-Substantive Change Request to OMB Control Number 0920-1109; Zika Emergency Package III: Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection

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Circumstances of Change Request for OMB 0920-1109

CDC requests approval for a non-substantive change to OMB Control No. 0920-1109: Zika Emergency Package III: Persistence of Zika virus in semen and urine of adult men with confirmed Zika virus infection.

The proposed changes are being made to Supporting Statement B to reflect the addition of two new documents:

- A letter from a State health department inviting individuals to participate in the study (Attachment K).
- A phone script for a State health department to invite individuals to participate in the study (Attachment L).

These additions are being sought because several states have expressed a preference to reach out to potential subjects by phone or mail to get their permission to share their contact info with CDC. The approved package only includes a phone script for CDC, not for state health departments.

There are no proposed changes to any information collection instruments and there is no impact on the public burden. The total number of estimated annualized burden remains 58.5 hours.

These amendments have been reviewed and approved by IRB (Attachment J2).

Attachments

A. Section 361 of the Public Health Service Act (42 USC 241)
B. 60-day FRN
C. Verbal Script for Consent and Introductory Survey
D. Follow-up Survey
E. Instructions for Sample Collection
F. Copy of Consent Form
G. General Questions
H. FAQs Sheet
I. Thank You and Test Results Letter
J. IRB Approval ***(updated)***
K. State Health department letter ***(new)***
L. State Health department phone script ***(new)***

Description of Changes

Approved Supporting Statement B

Zika virus disease is a nationally notifiable condition. CDC study staff will identify eligible potential participants through Zika surveillance efforts (Zikatracker or ArboNET) or through diagnostic testing services performed at CDC Fort Collins. For each case, they will contact the appropriate state (or jurisdiction) health department to request contact information (i.e. phone numbers) for the potential participant. CDC study staff will then contact the patient directly to explain the study and seek their consent to participate. Staff will call the case up to 6 times at the phone number provided. They will leave a voicemail on the 3rd and 4th attempts. Calls will occur at different times of the day on different days of the week, to increase the likelihood of contact. If state or local health officials feel that they must be engaged with the research, appropriate IRB amendments and approval will be sought.

Proposed changes to Supporting Statement B (changes highlighted)

Zika virus disease is a nationally notifiable condition. CDC study staff will identify eligible potential participants through Zika surveillance efforts (Zikatracker or ArboNET) or through diagnostic testing services performed at CDC Fort Collins. For each case, they will work with the appropriate state (or jurisdiction) health department to reach out to potential participants. Health department staff may make contact with eligible men in their state/jurisdiction by sending a letter (Attachment K) to them that briefly describes the study and asks the man to contact CDC directly if interested in participating. Alternately, health department staff may call the eligible man using a phone script (Attachment L) where they will briefly explain the study and ask the man if they would be OK having their contact information (name and telephone number) shared with CDC study staff. The study staff will then contact the patient directly to explain the study and seek their consent to participate. Staff will call the case up to 6 times at the phone number provided. They will leave a voicemail on the 3rd and 4th attempts. Calls will occur at different times of the day on different days of the week, to increase the likelihood of contact. If state or local health officials feel that they must be engaged with the research, appropriate IRB amendments and approval will be sought.