

Non-Substantive Change Request to OMB Control No. 0920-1118: Emergency Zika Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections

Program Contact

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**Circumstances of Change Request for OMB 0920-1118**

CDC requests approval for a non-substantive change to OMB Control No. 0920-1118: Emergency Zika Package V: Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika virus Infections

These changes are being made to improve comprehension of questions and flow of the interview. The project protocol has not changed. IRB review is not required.

Estimates of annualized burden hours for this change request remain the same. The burden estimate for the forms included in OMB Control No. 0920-1118 is 892 hours for the overall assessment, 67 hours of which are estimated for the Case-Control Interview section (Project 2).

**Description and Justification of Changes**

*Attachment E: Case-control Telephone Interview*

Changes to the questionnaire were based on pilot testing and a change in the expected data available from the dataset (we were unable to access the dataset until after IRB and OMB clearance had occurred). We adjusted the questionnaire to adapt to missing data.

Below we describe changes to the questionnaire and provide the rationale for changes. Additionally, a table is provided which shows the old version of questions side by side with the new version.

- Introductory script and questions: we added text to clarify that the interview would end if participants did not agree to participate, or if the wrong participant was selected.

- We removed a statement confirming the ZPK receipt date, as that data is not available in the dataset as expected. The introductory script was moved ahead of the question about Zika Prevention Kit (ZPK) receipt to adjust for this. Also, not receiving a ZPK is no longer a stop point, as ZPK receipt will also be assessed as part of the evaluation.
- The time period of interest in the current questionnaire is listed as the time between ZPK receipt and blood draw. However, the dataset did not include date of ZPK receipt; to adjust for this, we changed the questions to ask about the 3 months before blood draw. With this time period, we also removed sub-questions which asked if activities were performed/received before or after ZPK receipt (see Q2, Q2, Q20)
- Introductory question about ZPK receipt was broken into two questions – having heard of ZPKs, and having received a ZPK (requested to be Q1 and Q2).
- Q1, which asks about attending a WIC educational session for Zika, was moved after the ZPK section to keep ZPK questions together (requested to move to Q10).
- Q2, which asks about receiving educational materials from WIC, was moved after the ZPK section to keep ZPK questions together (requested to move to Q11).
- Q4: broken into three separate questions from the existing sub-bullets for formatting purposes (no text changed).
- Q5: removed (Some of the items in the kit may be items that you already had in your house and used. Others may be items that you didn't have or have never used before. BEFORE receiving the kit, when you were pregnant, how often did you use each of the following items?).
- Q6 and text were changed to ask about the 3 months before having blood drawn. The sub-question about using repellent from a ZPK was adjusted to only ask if the person received a ZPK. Identical changes were made to Q10, Q11.
- Q7: Text was changed to refer to “the same time period,” rather than repeating the same time period repeatedly. This is also true for Q8, Q9, Q10, Q11, Q12.
- Text before Q12 added reminder that all information will be confidential before beginning questions about sexual history.
- Q12-14: adjusted time frame to ask about three months before having blood drawn.
- Q15, 16, and 18 ask about ZPK item use and recommendations for improvement. The requested change moves these questions up to the ZPK section at the beginning of the survey (after current Q4) to have all ZPK questions in one section.

- Q20: changed to ask about the exact date, rather than reference to ZPK receipt.
- Intro to environmental section changed to refer to correct time period.
- Q27 moved before Q23 (in what zipcode did you live) as interviewers thought it made more sense to have the question about owning or renting at the beginning of the housing section.
- Q38: Added skip to ‘No’ response to assist interviewers.

<b>Current Question</b>	<b>Requested Changes - 1/23/21</b>
<p>Would you be willing to talk with me for a few minutes (less than 20 minutes) about your experience and the types of Zika prevention services you received in the past few months? It will help us know how we can do a better job of helping you and other pregnant women in Puerto Rico.</p> <p>No Yes, [If yes, are you over 18 years of age]</p>	<p>Would you be willing to talk with me for a few minutes (less than 25 minutes) about your experience and the types of Zika prevention services you received in the past few months? Everything we discuss will be kept confidential. It will help us know how we can do a better job of helping you and other pregnant women in Puerto Rico.</p> <p>No – thank you for your time! Have a nice day. [End interview] Yes, [If yes, are you over 18 years of age]</p>
<p>Your doctor reported that you had blood drawn for a Zika test on &lt;specimen collection date&gt;. Is that correct?</p> <p>No Yes – continue</p>	<p>Your doctor reported that you had blood drawn for a Zika test on &lt;specimen collection date&gt;. Is that correct?</p> <p>No [Stop the interview] Yes – continue</p>
<p>I also see here that you received information or materials about Zika Prevention Kit from WIC on &lt;ZPK receipt date&gt;. Is that correct?</p> <p>No or if unsure what ZPKs are: The Zika Prevention Kit is a tote bag that contains educational information from the Puerto Rico Health Department and the Centers for Disease Control and Prevention about how to prevent Zika infection while you are pregnant along with items that could help prevent Zika virus infection. Items in the kit include: a mosquito bed net, mosquito repellent, condoms, and some include mosquito dunks (larvicide) and thermometers.</p>	<p>First, I’d like to ask you questions about materials or supplies you might have received from the WIC program.</p> <p>1. Have you heard of Zika Prevention Kits?  <input type="checkbox"/> Yes continue to question 2 (ZPK receipt)  <input type="checkbox"/> No  No or if unsure what ZPKs are: The Zika Prevention Kit is a tote bag that contains educational information from the Puerto Rico Health Department and the Centers for Disease Control and Prevention about how to prevent Zika infection while you are pregnant along with items that could help prevent Zika virus infection. Items in the kit include:</p>

<p>Do you remember receiving anything like that?  No – stop interview  Yes – Great!</p>	<p>a mosquito bed net, mosquito repellent, condoms, and some include mosquito dunks (larvicide) and thermometers.</p> <p>2. Have you received a Zika Prevention Kit?  <input type="checkbox"/> No – skip to Q11 (Did you attend an educational session about Zika?)  <input type="checkbox"/> Yes  What day did you receive the ZPK?  Date: _____</p>
<p>4. Did you open your Zika Prevention Kit?  Yes</p> <p>a. What did the information in the kit say you need to do? (Probe for use repellents, use bed net, use condoms, etc.)</p> <p>a. Use insect repellent  b. Sleep under bed net  c. Put mosquito dunks in standing water  d. Use condoms/don't have unprotected sex  e. Go to doctor if ill  f. Other, please specify: _____</p> <p>b. What items were included in the kit? (Do not read, tick all mentioned)</p> <p>Repellent  Bed net  Mosquito dunks  Condom(s)  Thermometer  Educational materials  Other, please specify:</p> <p>No, why not?  Refused</p>	<p>4. Did you open your Zika Prevention Kit?  <input type="checkbox"/> No (skip to Q7, educational session)  Why not?  _____</p> <p><input type="checkbox"/> Refused  <input type="checkbox"/> Yes</p> <p>5. What did the information in the kit say you need to do? (Probe for use repellents, use bed net, use condoms, etc.) [Don't read options – wait for response]</p> <p><input type="checkbox"/> Use insect repellent  <input type="checkbox"/> Sleep under bed net  <input type="checkbox"/> Put mosquito dunks in standing water  <input type="checkbox"/> Use condoms/don't have unprotected sex  <input type="checkbox"/> Go to doctor if ill  <input type="checkbox"/> Other, please specify: _____</p> <p>6. What items were included in the kit? (Do not read, tick all mentioned)</p> <p><input type="checkbox"/> Repellent  <input type="checkbox"/> Bed net  <input type="checkbox"/> Mosquito dunks  <input type="checkbox"/> Condom(s)  <input type="checkbox"/> Thermometer  <input type="checkbox"/> Educational materials  <input type="checkbox"/> Other, please specify:  _____</p>
<p>Now, I'm going to ask more questions about your use of these items AFTER receiving the kit, but before you got blood drawn for the Zika</p>	<p>Now, I'm going to ask more questions about your activities in the 3 months before you got blood drawn for the Zika test. It might be</p>

<p>test. For most of the questions, I'll be asking from now on, think about what you did in that period of time.</p>	<p>helpful to look at a calendar to help remember this time period. For most of the questions, I'll be asking from now on, think about what you did in that period of time.</p>
<p>6. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, how often did you put mosquito repellent on skin that was not covered by clothing?</p> <p>Never or almost never Seldom or rarely Sometimes Often Usually or most of the time Always or almost always Refused</p> <p>If yes to any repellent use: Did you use the repellent from the ZPK?</p> <p>Yes No Refused</p>	<p>12. During the time three months before you had blood drawn for the Zika test, how often did you put mosquito repellent on skin that was not covered by clothing?</p> <p>Never or almost never Seldom or rarely Sometimes Often Usually or most of the time Always or almost always Refused</p> <p>12a. If yes to any repellent use and received ZPK: Did you use the repellent from the ZPK?</p> <p>Yes No Refused</p>
<p>7. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, how often did you wear long pants?</p> <p>a. Never or almost never b. Seldom or rarely c. Sometimes d. Often e. Usually or most of the time f. Always or almost always g. Refused</p>	<p>13. During that same time, how often did you wear long pants?</p> <p>a. Never or almost never b. Seldom or rarely c. Sometimes d. Often e. Usually or most of the time f. Always or almost always g. Refused</p>
<p>8. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, how often did you wear a long-sleeved shirt?</p> <p>a. Never or almost never b. Seldom or rarely c. Sometimes d. Often e. Usually or most of the time f. Always or almost always</p>	<p>14. During that same time, how often did you wear a long-sleeved shirt?</p> <p>a. Never or almost never b. Seldom or rarely c. Sometimes d. Often e. Usually or most of the time f. Always or almost always g. Refused</p>

<p>g. Refused</p> <p>9. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, how often did you or somebody else in your household remove accumulated water and cover up or screen water containers inside and around your home (on your property)?</p> <p>a. Never or almost never  b. Seldom or rarely  c. Sometimes  d. Often  e. Usually or most of the time  f. Always or almost always  g. Refused</p>	<p>15. During that same time, how often did you or somebody else in your household remove accumulated water and cover up or screen water containers inside and around your home (on your property)?</p> <p>o. Never or almost never  p. Seldom or rarely  q. Sometimes  r. Often  s. Usually or most of the time  t. Always or almost always  u. Refused</p>
<p>10. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, did you ever put a mosquito dunk, or larvicide, in accumulated water around your home?</p> <p>a. Never or almost never  b. Seldom or rarely  c. Sometimes  d. Often  e. Usually or most of the time  f. Always or almost always  g. Refused</p> <p>If yes, did you use the mosquito dunk from the Zika Prevention Kit?</p> <p>Yes  No  Refused</p>	<p>16. During that same time, did you ever put a mosquito dunk, or larvicide, in accumulated water around your home?</p> <p>v. Never or almost never  w. Seldom or rarely  x. Sometimes  y. Often  z. Usually or most of the time  aa. Always or almost always  bb. Refused</p> <p>16a. If yes and received ZPK, did you use the mosquito dunk from the Zika Prevention Kit?</p> <p>Yes  No  Refused</p>
<p>11. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, did you usually sleep under a mosquito net when you slept or took a nap?</p> <p>a. Never or almost never  b. Seldom or rarely  c. Sometimes  d. Often  e. Usually or most of the time  f. Always or almost always</p>	<p>17. During that same time, did you usually sleep under a mosquito net when you slept or took a nap?</p> <p>a. Never or almost never  b. Seldom or rarely  c. Sometimes  d. Often  e. Usually or most of the time  f. Always or almost always  g. Refused</p>

<p>g. Refused</p> <p>If yes, did you use the mosquito net from the Zika Prevention Kit?</p> <p>Yes</p> <p>No</p> <p>Refused</p>	<p>17a. If yes and received ZPK, did you use the mosquito net from the Zika Prevention Kit?</p> <p>Yes</p> <p>No</p> <p>Refused</p>
<p>The next questions are about sexual relations with your husband or male partner.</p>	<p>The next questions are about sexual relations with your husband or male partner. Again, everything we discuss will be confidential.</p>
<p>12. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, did you have sexual intercourse [that is, vaginal, anal, or oral (mouth-to-penis) sex] with your male partner?</p> <p>No,</p> <p>After recording response, go to question 15</p> <p>Yes</p> <p>Prefer not to answer</p>	<p>18. During the three months before you had blood drawn for the Zika test, did you have sexual intercourse [that is, vaginal, anal, or oral (mouth-to-penis) sex] with your male partner?</p> <p>No,</p> <p>After recording response, go to question 21</p> <p>Yes</p> <p>Prefer not to answer</p>
<p>13. When you had sex during the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, how often did you use a condom?</p> <p>Every time I had sex Go to question 14</p> <p>Sometimes when I had sex Go to question 14</p> <p>I never used a condom when I had sex Go to question 15</p> <p>Prefer not to answer</p>	<p>19. When you had sex during that same time, how often did you use a condom?</p> <p>Every time I had sex Go to question 22</p> <p>Sometimes when I had sex Go to question 22</p> <p>I never used a condom when I had sex Go to question 23</p> <p>Prefer not to answer</p>
<p>14. Did you use condoms from the Zika Prevention Kit?</p> <p>Yes</p> <p>No</p> <p>Refused</p>	<p>20. If used condoms and received ZPK, Did you use condoms from the Zika Prevention Kit?</p> <p>Yes</p> <p>No</p> <p>Refused</p>
<p>15. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, did you use up any of the items that were included in the Zika prevention kit? (or have you needed to replace any items that came in the kit?) Which items?</p> <p>Yes, which items</p> <p>Repellent</p> <p>Condoms</p>	<p>7. Did you use up any of the items that were included in the Zika prevention kit? Which items?</p> <p>Yes, which items</p> <p>Repellent</p> <p>Condoms</p> <p>Mosquito dunks (or other larvicide)</p> <p>Mosquito bed net</p> <p>No – skip to Q9</p>

<p>Mosquito dunks (or other larvicide)  Mosquito bed net  No  Don't know/not sure  Refused</p>	<p>Don't know/not sure  Refused</p>
<p>16. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, did you purchase any items to replace the items in the kit that you used up (or needed to replace)?</p> <p>Yes, which items  Repellent  Condoms  Mosquito dunks (or other larvicide)  Mosquito bed net</p> <p>No, why not?  Do not have money to buy  Items are too expensive (too costly)  Am embarrassed to buy (e.g., condoms)  Do not feel I need them (they don't offer protection)  Other, please specify:</p> <p>Don't know/not sure  Refused</p>	<p>8. Did you purchase any items to replace the items in the kit that you used up (or needed to replace)?</p> <p>Yes, which items  Repellent  Condoms  Mosquito dunks (or other larvicide)  Mosquito bed net</p> <p>No, why not?  Do not have money to buy  Items are too expensive (too costly)  Am embarrassed to buy (e.g., condoms)  Do not feel I need them (they don't offer protection)  Other, please specify: _____</p> <p>Don't know/not sure  Refused</p>
<p>17. Is there anything that we haven't discussed that you have been doing to reduce the risk of mosquito bites to avoid getting Zika virus during the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test?</p> <p>No  Yes, What?</p> <p>Staying indoors  I moved to/spend more time in another location with fewer mosquitoes, or better housing  I have sprayed my house with pesticide by myself or my family  I have had a business come spray my house  Burn mosquito coils  Use mosquito zapper rackets</p>	<p>21. Is there anything that we haven't discussed that you have been doing to reduce the risk of mosquito bites to avoid getting Zika virus during the three months before you had blood drawn for the Zika test?</p> <p>No  Yes, What?</p> <p>Staying indoors  I moved to/spend more time in another location with fewer mosquitoes, or better housing  I have sprayed my house with pesticide by myself or my family  I have had a business come spray my house  Burn mosquito coils  Use mosquito zapper rackets</p>

<p>Other, please specify: Refused</p>	<p>Other, please specify: Refused</p>
<p>20. Did you receive spraying services at your home? (or has your home been sprayed already?) Yes When did the spraying services occur? Did they occur...     Before you received a Zika Prevention Kit?     After you received a Zika Prevention Kit but before you got your blood drawn?     After you received a Zika Prevention Kit AND after you got your blood drawn? No     Don't know/not sure Refused</p>	<p>23. Did you receive spraying services at your home? (or has your home been sprayed already?) Yes When did the spraying services occur?     Date: _____ No     Don't know/not sure Refused</p>
<p>Questions about mosquitoes in their environment (environmental stimuli)</p> <p>For all the questions I'm about to ask, try to think about the time from when you received the Zika Prevention Kit to when you had blood drawn.</p>	<p>Questions about mosquitoes in their environment (environmental stimuli)</p> <p>For all the questions I'm about to ask, try to think about the three months before you had blood drawn.</p>
<p>27. Do you currently rent or own your home? Own Rent Occupy without paying rent (live with family or friend) Live in public housing Other, please specify: Refused</p>	<p>26. In those three months, did you rent or own your home? Own Rent Occupy without paying rent (live with family or friend) Live in public housing Other, please specify: Refused</p>
<p>34. During the time between when you received the Zika prevention kit and when you had blood drawn for the Zika test, did any members of your household have an illness with rash, fever, or body pain? No Yes How many people were ill? _____ Did this include your sex partner or husband? _____ Were they tested for Zika? No</p>	<p>37. During the three months before you had blood drawn for the Zika test, did any members of your household have an illness with rash, fever, or body pain? No [Skip to question 38] Yes How many people were ill? _____ Did this include your sex partner or husband? _____ Were they tested for Zika? No Don't know/not sure</p>

<p>Don't know/not sure  Refused  Yes</p> <p>Did a healthcare provider tell them they had Zika?</p> <p>Yes</p> <p>No  Don't know/not sure  Refused</p>	<p>Refused  Yes</p> <p>Did a healthcare provider tell them they had Zika?</p> <p>Yes</p> <p>No  Don't know/not sure  Refused</p>
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**Estimates of Annualized Burden hours (unchanged from approved ICR)**

Estimates of annualized burden hours for this change request remain the same. The burden estimate for the forms included in OMB Control No. 0920-1118 is 892 hours for the overall assessment, 67 hours of which are estimated for the Case-Control Interview section (Project 2).

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Burden Hours
Project 1					
Pregnant WIC participant	Initial Telephone Interview	1,800	1	20/60	600
	Follow-up Telephone Interview	900	1	15/60	225
Project 2					
Pregnant WIC participant	Telephone interview of cases and controls	200	1	20/60	67
					892