

ICR Non-Substantive CHANGE REQUEST MEMO

ICR Title

OMB NO. 0920-0010

Expiration Date 02/28/2023

Summary:

The computer-assisted telephone interview asks participants if they have ever been told by a healthcare provider that they have any of 14 specific infections. This non-substantive change adds an additional infection to that list so that participants will now be asked about 15 specific infections. Subjects will be asked whether they were told by a healthcare provider that they had coronavirus or COVID-19. If the participant reports that they had this infection they will be asked when it was diagnosed, whether they had symptoms during pregnancy, and whether any medication was used to treat the infection. This change is being made so that we can capture information on these infections in our study population of women who were pregnant during the SARS-CoV-2 pandemic.

An additional minor change is being made to add a script prompt at the end of the interview for a specific set of participants who are only eligible for one subsequent part of the study. The existing prompts do not accommodate this subset of participants.

Both changes are being made to the English and Spanish instruments.

Attachments:

- AttF1_BDSTEPS_CATI_V8.0
- AttF1_BDSTEPS_CATI_V8.0_SPAN

Background & Justification:

The study population consists of women who had a pregnancy ending January 1, 2020 or later. Therefore, in the coming months it is likely that there will be many participants who experienced a COVID-19 infection. Given that SARS-CoV-2 is a novel coronavirus, its impact on pregnancy is largely unknown, and BD-STEPS provides a unique opportunity to better understand the potential impact of infection during pregnancy on the health of pregnant women and their infants.

Effect of Proposed Changes on Current Approved Instruments:

Form	Current/Question Item	Requested Change
AttF1_BDSTEPS_CATI_V8.0 AttF2_BDSTEPS_CATI_V8.0_SPAN	T1. Has a doctor or other health care provider <u>ever</u> told you that you had any of the following infections? <ul style="list-style-type: none">- Zika virus- Chikungunya- Dengue- Lyme disease- Malaria- West Nile- Hepatitis A- Hepatitis B- Hepatitis C- HIV- Syphilis	T1. Has a doctor or other health care provider <u>ever</u> told you that you had any of the following infections? <ul style="list-style-type: none">- Coronavirus or COVID-19- Zika virus- Chikungunya- Dengue- Lyme disease- Malaria- West Nile- Hepatitis A- Hepatitis B- Hepatitis C- HIV

ICR Non-Substantive CHANGE REQUEST MEMO

	<ul style="list-style-type: none"> - Chlamydia - Gonorrhea - Human papillomavirus (HPV) - Any other sexually transmitted disease, such as herpes or trichomoniasis? 	<ul style="list-style-type: none"> - Syphilis - Chlamydia - Gonorrhea - Human papillomavirus (HPV) - Any other sexually transmitted disease, such as herpes or trichomoniasis?
<p>AttF1_BDSTEPS_CATI_V8.0 AttF2_BDSTEPS_CATI_V8.0_SPAN</p>	<p>HH8. FOR HH8, INTERVIEWERS WILL NEED TO USE STATE AND INFANT STATUS TO DETERMINE WHICH SCRIPT TO USE:</p> <p>HH8. <u>FOR CENTERS THAT ARE COLLECTING BLOODSPOTS (STATE AR, IA, MA, NY, NC) AND A LIVEBORN INFANT:</u> That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we will mail you two consent forms. One of the forms asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. The other form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to return the consent forms, we will send you a \$10 gift card for each consent form returned as a token of appreciation for your continues interest in our study.</p>	<p>FOR HH8, INTERVIEWERS WILL NEED TO USE STATE AND INFANT STATUS TO DETERMINE WHICH SCRIPT TO USE:</p> <p>HH8. <u>FOR CENTERS THAT ARE COLLECTING BLOODSPOTS (STATE AR, IA, MA, NY, NC) AND A LIVEBORN INFANT:</u> That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we will mail you two consent forms. One of the forms asks for your permission to request leftover newborn bloodspots that were already collected shortly after your baby's birth by your state's newborn screening program. This part of the study will help us to understand the role genetic and other biologic factors have in causing birth defects. The other form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to return the consent forms, we will send you a \$10 gift card for each consent form returned as a token of appreciation for your continues interest in our study.</p>

ICR Non-Substantive CHANGE REQUEST MEMO

	<p><u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA) OR FOR A NON-LIVEBORN INFANT:</u> That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. So that we may contact you in the future we would like to confirm your address. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we will mail you a consent form. The consent form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to sign and send back the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.</p>	<p><u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA) OR FOR A NON-LIVEBORN INFANT:</u> That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. So that we may contact you in the future we would like to confirm your address. To thank you for your time, we will send you a \$30 gift card. Along with the gift card, we will mail you a consent form. The consent form asks for your permission to request your infectious disease information that was already reported by your physician to your state's health department. This information will be used to study how infectious diseases may play a role in why some babies have birth defects. If you choose to sign and send back the consent form, we will send you a \$10 gift card as a token of appreciation for your continued interest in our study.</p> <p><u>FOR STILLBIRTHS WITHOUT A BIRTH DEFECT (AR, MA CENTERS):</u> That completes the interview, but as you read in the advance packet, you may be asked to participate in other parts of the study. So that we may contact you in the future we would like to confirm your address. To thank you for your time, we will send you a \$30 gift card.</p>
<p>AttF1_BDSTEPS_CATI_V8.0 AttF2_BDSTEPS_CATI_V8.0_SPAN</p>	<p>HH10. FOR HH10, INTERVIEWERS WILL NEED TO USE STATE AND INFANT STATUS TO DETERMINE WHICH SCRIPT TO USE:</p> <p>HH10. <u>FOR CENTERS THAT ARE COLLECTING BLOODSPOTS (STATE: AR: AR, IA, MA, NY, NC) AND A LIVEBORN INFANT:</u> In the</p>	<p>HH10. FOR HH10, INTERVIEWERS WILL NEED TO USE STATE AND INFANT STATUS TO DETERMINE WHICH SCRIPT TO USE:</p> <p>HH10. <u>FOR CENTERS THAT ARE COLLECTING BLOODSPOTS (STATE: AR: AR, IA, MA, NY, NC) AND A LIVEBORN INFANT:</u> In the</p>

ICR Non-Substantive CHANGE REQUEST MEMO

	<p>introductory letter we sent you, there was a \$20 gift card included as a token of appreciation for your interest. As I just mentioned, you will be sent a \$30 gift card to thank you for your time to complete the interview, and you will have the opportunity to receive additional gift cards after you sign and return the consent forms to access your child's newborn blood spots and your infectious disease information. We cannot promise you will get a gift card from your chosen store, but could you tell me which one of the following stores you would prefer? [READ LIST]</p> <p><u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA) OR A NON-LIVEBORN INFANT:</u> In the introductory letter we sent you, there was a \$20 gift card included as a token of appreciation for your interest. As I just mentioned, you will be sent a \$30 gift card to thank you for your time to complete the interview, and you will have the opportunity to receive an additional gift card after you sign and return the consent form to access your infectious disease information. We cannot promise you will get a gift card from your chosen store, but could you tell me which one of the following stores you would prefer? [READ LIST]</p> <ul style="list-style-type: none">- Amazon- Target- Wal-Mart- CVS	<p>introductory letter we sent you, there was a \$20 gift card included as a token of appreciation for your interest. As I just mentioned, you will be sent a \$30 gift card to thank you for your time to complete the interview, and you will have the opportunity to receive additional gift cards after you sign and return the consent forms to access your child's newborn blood spots and your infectious disease information. We cannot promise you will get a gift card from your chosen store, but could you tell me which one of the following stores you would prefer? [READ LIST]</p> <p><u>FOR CENTERS THAT ARE NOT COLLECTING BLOODSPOTS (STATE: CA, GA) OR A NON-LIVEBORN INFANT:</u> In the introductory letter we sent you, there was a \$20 gift card included as a token of appreciation for your interest. As I just mentioned, you will be sent a \$30 gift card to thank you for your time to complete the interview, and you will have the opportunity to receive an additional gift card after you sign and return the consent form to access your infectious disease information. We cannot promise you will get a gift card from your chosen store, but could you tell me which one of the following stores you would prefer? [READ LIST]</p> <p><u>FOR STILLBIRTHS WITHOUT A BIRTH DEFECT (AR, MA CENTERS):</u> In the introductory letter we sent you, there was a \$20 gift card included as a token of appreciation for your interest. As I just mentioned, you will be sent a \$30 gift card to thank you for your time to complete the interview. We</p>
--	---	---

ICR Non-Substantive CHANGE REQUEST MEMO

		<p>cannot promise you will get a gift card from your chosen store, but could you tell me which one of the following stores you would prefer? [READ LIST]</p> <ul style="list-style-type: none"> - Amazon - Target - Wal-Mart - CVS
--	--	--

Effect on Burden Estimate:

Discuss and include a table comparing to previously approved burden

- *Include a burden table and identify changes, or, if the burden isn't changing, state there is no change*

Form	Approved Burden	Requested Burden
AttF1_BDSTEPS_CATI_V8.0 AttF2_BDSTEPS_CATI_V8.0_SPAN	4,433 hours	There is no change
Total		