Form Approved
OMB No. 0920-1154
Exp. Date: 1/31/2020

CONSENT FORM FOR PARTICIPATION IN RESEARCH:

"Messaging to Improve Patient-Provider Communication and Engagement on Risks of Alcohol Use During Pregnancy"

American Institutes for Research/Eureka Facts

This is a verbal consent that will be read to the participant.

Introduction:

Hello, my name is _____ and I am a researcher with a social science research company called EurekaFacts conducting a project in collaboration with the American Institutes for Research (AIR) on behalf of the Centers for Disease Control and Prevention. Thank you for agreeing to speak with me today and answer my questions.

I wanted to talk to you today because you recently answered a survey about practices related to alcohol screening and brief intervention (or alcohol SBI) with your female patients. The purpose of this in-depth interview is to further understand your clinical practices with your female patients regarding risky alcohol use. Your responses to this interview will help us improve communication materials to help providers like you talk about risky alcohol use and reduce the prevalence of fetal alcohol spectrum disorders.

Now, before we continue, it is important that you know that, as part of the research team, I am neutral on this topic. I am interested in getting your point of view to understand what clinicians' perspectives are on current alcohol SBI procedures. As a neutral researcher, I am simply trying to learn more about different views people may have. Please keep in mind that there are no 'right' or 'wrong' answers.

There are no known risks to participating in this study. No more than minimal risk is expected during any phase of this study. Some individuals might experience discomfort when talking about sensitive topics like alcohol use, contraception (birth control), and pregnancy. You may choose to refuse to answer any question and stop the interview at any time during the interview.

You may not directly benefit from this research; however, we hope that your participation in the study may help CDC assess its outreach efforts to healthcare providers and improve patient communication materials about this important topic as well as to understand any other informational needs healthcare providers may have.

Public reporting burden of this collection information is estimated to average 8 minutes, including completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, GA 30333: ATTN: PRA (0920-1154).

The information you are being asked to provide is authorized to be collected under the System of Records Notices 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. The principal purpose for which CDC will use the information that you provide is to inform the development of patient and healthcare provider messages and materials about alcohol use during pregnancy. The information you provide will be included in a Privacy Act system of records, and will be used and may be disclosed for the purposes and routine uses described and published in the following System of Records Notice (SORN): 09-20-0136: Epidemiologic Studies and Surveillance of Disease Problems, [Federal Register: December 31, 1992 (Volume 57, Number 252)] [Notices] [Page 62812-62813]

I anticipate that our conversation should last around 30 minutes today. You will receive an incentive of $100 (or equivalence in points) as a token of appreciation for your participation from the panel provider, Dynata. I will be taking notes and also recording our conversation with your permission, but everything that you tell me will be kept confidential and treated in a secure manner. Your answers in this study will remain private. By agreeing to participate in this interview, you are allowing CDC to use the information from this study. The information collected is for research only, and your name will not be shared with anyone outside of this study, except as otherwise required by law. The only instance when we would release information about you to anyone outside the project would be if we were required to do so by law, such as a subpoena or if we learned someone were in danger of harm. Any results that come from this study will be presented as an aggregate and your name will not be linked to your answers.

Your participation in this study is completely voluntary and you can stop at any time. You are free to skip any question that you choose. There will not be any penalties if you refuse to participate in this study or refuse to answer any questions.

This survey has been approved by AIR's IRB. If you have any questions, please contact Dr. Hanno Petras (Project Director) at hpetras@air.org or at 202-403-5639 or Erin Morrison Wallace (IRB Chair) at ewallace@air.org or at 202-403-5542.

Do you agree that you are at least 18 years old, have read and understood this consent form, and agree to participate in this research study?

☐ Yes → If Yes, continue
☐ No → If No, Excuse and use Script A (at end of document)

Do you consent to having this conversation recorded?

☐ Yes → If Yes, continue
☐ No → If No, Excuse and use Script A (at end of document)

For participants who CURRENTLY or USED TO deliver alcohol SBI:

Alcohol screening and brief intervention, or alcohol SBI, has two components: 1) a validated set of screening questions to identify patients' drinking patterns and 2) a short conversation with patients who are drinking too much and, for patients at severe risk, a referral to specialized treatment.

Do you currently deliver alcohol SBI?

☐ Yes → If Yes, begin interview
☐ No → If No, continue

Have you ever delivered alcohol SBI in the past?

☐ Yes → If Yes, continue to interview
☐ No → If No, Excuse and use Script B (at end of document)

For participants who have NEVER delivered alcohol SBI:

Alcohol screening and brief intervention, or alcohol SBI, has two components: 1) a validated set of screening questions to identify patients' drinking patterns and 2) a short conversation with patients who are drinking too much and, for patients at severe risk, a referral to specialized treatment.

Have you ever delivered alcohol SBI, now or in the past?

☐ Yes → If Yes, Excuse and use Script C (at end of document)
☐ No → If No, begin interview

Termination Scripts

Script A – Termination for lack of consent to participate or record

Thank you so much for agreeing to talk with me today. I need your consent to participate or record the interview, and so we will stop this interview, I appreciate your willingness to answer my questions, and those are all the questions I have at the moment. Have a great day.

Script B – Termination for never having delivered alcohol SBI (when we want people who currently or used to deliver it)

Thank you so much for agreeing to talk with me today. Since all of my questions have to do with alcohol screening and brief intervention, I need to speak **with people who currently deliver it or have delivered it in the past**. I appreciate your willingness to answer my questions, and those are all the questions I have at the moment. Have a great day.

Script C – Termination for having delivered alcohol SBI (when we want people who have never delivered it)

Thank you so much for agreeing to talk with me today. Since all of my questions have to do with alcohol screening and brief intervention, I need to speak with people who **have never** delivered it. I appreciate your willingness to answer my questions, and those are all the questions I have at the moment. Have a great day.