APPENDIX 10: PREGNANT AND POST-PARTUM WOMEN PILOT CONSENT

Maternal Alcohol Reduction Intervention in South Africa

[MaRISA]

INFORMATION AND CONSENT

Introduction

Hello. My name is_____. I am from the South African Medical Research Council (SAMRC). We are asking you to take part in our study. Before you agree to take part, you should understand what it involves. The information in this consent form is to help you decide if you would like to take part in this study. If you have any questions, which are not fully explained in this document, please do ask the study staff. You should not agree to take part unless you are happy about all that is involved.

Why are we doing this?

We want to examine the acceptability and feasibility of a technology-based behavioral intervention to encourage alcohol abstinence during pregnancy and lactation through use of contingent awards.

What We're Asking of You

Today-

We will ask you to answer some questions about yourself, your personal life and relationships, your health, your pregnancy and/or breastfeeding and your mental well-being. The interview should take approximately 50-60 mins to complete. We will also ask you for contact information so that we can stay in touch with you during the study. We will provide you with instructions on how to use the mobile breathalyzer including the text message alerts that will be sent as reminders twice a day to solicit breath samples and describe how your breath samples will be transmitted and displayed on the company portal OR what is required so that you can come to the healthcare facility twice a week to provide urine samples for alcohol testing.

Over the next 3 months-

We will continue to send text messages and reminders about clinic visits to provide urine samples or to prompt you to provide a breath sample twice a day during which the breathalyzer will automatically take a photo of your face while providing a breath sample and will send the BAC, the face photo, and geographical location to the Soberlink's password-protected website. We will provide ongoing technical support and referral where needed. You will receive financial incentives for each alcohol-negative samples. We will also send weekly text messages with information about total earnings, health promotion and referral content.

In 6 weeks and 3 months' time-

We will conduct an interview about your health, your pregnancy and/or breastfeeding and your mental well-being.

After birth (if pregnant)-

We will collect birth outcome information from your medical record at the clinic including: Weight, height, head circumference, gestational age, NICU admission, length of stay, Apgar scores, etc.

Postpartum follow-ups-

We will collect infant outcomes information from your medical record at the clinic as well as at the follow-up appointment including: Infant weight, height, head circumference, medical records of emergency room visits, pediatric visits, and hospitalization.

Potential Risks and Discomforts.

There are some risks to taking part in this study. Some of the questions may make you feel uncomfortable. You will never be pressured to answer the questions. It is okay if you do not want to talk about certain topics. You can also take a break at any time. Participation is fully voluntary. In the event that you do experience any mental or emotional discomfort, experienced study staff will assist in getting you the appropriate support services. You may also feel uncomfortable or nervous providing urine or breath samples. In case of using a breathalyzer, study staff will provide you with step-by-step instructions on using the mobile breathalyzer and explain how the breath sample will be transmitted and displayed on the company website. Research staff will also contact you during the first week to ask if you are comfortable or experiencing any issues with the technology. There will be no repercussions for any positive samples submitted except that magnitude of the incentive reverts to the initial amount until you provide 4 consecutive alcohol-negative breath samples or 2 consecutive alcohol-negative urine samples. The outcome of samples submitted will not be shared with anyone outside the research team and will not affect your usual antenatal or post-partum care at your healthcare facility.

Potential Benefits of Taking Part in the Study.
If you choose to take part in this study, you may make healthier choices for you and your infant. Your feedback will also help us improve the provision of this intervention.

Confidentiality and Privacy.
Any information obtained will remain confidential. It will be disclosed only as required by law in the following two instances: 1) If you tell us that you are about to hurt yourself or someone else 2) or if you are involved in the neglect and/or abuse of a child. In either case, we have to report that information to the appropriate authorities. All the forms we complete are stored on password protected and encrypted computer servers. The MRC ethics committee will however have access to all data. The pilot trial is registered with ClinicalTrials.gov where de-identified clinical trial information will be posted.

Participation and Withdrawal.
Participation is voluntary. You can choose not to participate. If you decide to participate, you may choose to stop your participation at any time. There will be no consequences. Your decision to take part or not take part in this study will not affect your usual antenatal or post-partum care at your healthcare facility. You may also refuse to answer any questions you do not want to answer.

Who is funding the study?
The study is being conducted by the South African Medical Research Council and RTI International and funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH).

Reimbursement
Today for your time you will receive R150 via a mobile cash-send mechanism.

Over the next 3 months you will be able to earn financial rewards contingent on alcohol abstinence. Each alcohol-negative sample will result in R1 and increase by R1 until R20. You will receive a PIN with which you can withdraw cash weekly via an ATM. If you provide alcohol-negative samples for all potential submission opportunities during the 3-month intervention, you could earn up to R1,590. If you miss a sampling opportunity or provides alcohol-positive samples, you will not earn the incentive, and the magnitude of the incentive goes back to R1 until you provide 4 consecutive alcohol-negative breath samples or 2 consecutive alcohol-negative urine samples, equaling 2 days of alcohol abstinence.

At 6 week and 3 months, for your time, you will receive R150 via a mobile cash-send mechanism and a further R150 for returning the breathalyzer device for research staff to pick up if you are asked to use the breathalyzer instead of or together with urine testing.

Who to Contact with Questions.
This study has been approved by the South African MRC Ethics Committee. The study will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, and the South African Guidelines for Good Clinical Practice.

If you have any questions or concerns about the research, please contact Dr Yukiko Washio Principal investigator: ywashio@rti.org or Dr Petal Petersen-Williams Site Principal Investigator

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Rights of Research Participants
You can decide you do not want to participate at any time. If you have any questions about your rights as a participant, you can contact the chairperson of the MRC ethics committee, Ms. Adri Labuschagne at 021 938 0687 or email: adri.labuschagne@mrc.ac.za.

Indicating Consent
Please let us know if you have any questions before signing this consent form. Please initial next to each item to show that you agree to what is required:

Agree	
	I agree to continue in the study, which has been fully described to me. This means that I agree to answer questions today
	I agree to provide my contact information
	I agree to take provide breath samples when prompted twice a day and for my photo to be taken
	I agree to receive daily text-message reminder to submit samples and weekly text messages
	I agree for my medical records to be retried in order to record birth and infant outcomes
	I understand that 6 weeks from now I will be contacted for a follow-up interview
	I understand that 3 months from now I will be contacted for a follow-up interview
	I understand that my participation in this study is completely voluntary, and there will be no penalty if I choose not to participate.

In accordance with the provisions of the **Protection of Personal Information Act 4 of 2013** (as amended), I hereby consent:

a. To my personal information (hereinafter 'data') being collected, processed, shared and stored in accordance with the research protocol as approved by the South African Medical Research Council's Human Research Ethics Committee (SAMRC HREC);
b. To my anonymised data being shared, processed and transferred by third parties and between third parties, and where relevant beyond the jurisdictional borders of South Africa;
c. To all findings and results flowing from my anonymised data being broadly shared and published on the conclusion of the research.

DECLARATION BY PARTICIPANT

By signing below, I, _____ ***(Participant's Full Name*)** agree to take part in the MRC Study.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressured to take part. I also understand that I do not give up any rights by signing below.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I have a copy of the consent form with the information about rights of research participants and who to contact with questions.

Participant's Signature	**Date**	**Signed at (Place)**
	(DD/MM/YYYY)	

Declaration by staff

I, _____ ***(Project Staff's Full Name***) declare that:

- I explained the information in this document to _____
  (Participant's Full Name)
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that s/he adequately understands all aspects of the research
- I gave him/her a card with information about rights of research participants and who to contact with questions.

Project staff's Signature	**Date**	**Signed at (Place)**
	(DD/MM/YYYY)	