April 11, 2024

NCT05747599

# Adapting and Testing a Behavioural Intervention to Prevent FASD and Adverse Infant Outcomes (MaRISA+)

# APPENDIX 3

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes***

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 because you are either pregnant, or postpartum with a recent history of alcohol and tobacco/cannabis use. The information in this consent form will give you the necessary details about this study to help you decide whether you would like to take part or not. 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 adapt and test an intervention to decrease polysubstance use (i.e., alcohol and tobacco/cannabis) during pregnancy and breastfeeding and to prevent adverse clinical outcomes, including Fetal Alcohol Spectrum Disorders (FASD).

**What We're Asking of You**

If you agree to participate, you will be one of 48 women (24 pregnant and 24 postpartum women) who have a recent history of using alcohol, tobacco, or cannabis during your current pregnancy or while you are breastfeeding. You will be required to complete 3 interviews as part of your participation: a screening interview, a baseline interview, and a 3-month follow-up interview. While enrolled in the study, you will be asked a series of questions during these 3 interview appointments. In addition, you will be asked to provide a blood sample and a urine sample at screening and once per month until the completion of your time in the study. You will also be asked to participate in a **Post-testing qualitative interview.** You will spend approximately one hour at each interview. Your time and inputs are very important to us since they will help us improve this program for future studies.

**Potential Risks and Discomforts.**

We don't anticipate any risks associated with taking part in this study. You might, however, feel uncomfortable providing biological samples or responding to certain interview questions. If you feel uncomfortable, please let a member of the study staff know. We want you to be aware that you will never be pressured to answer any questions or forced to provide biological samples. Participation is fully voluntary. You have the right to stop participation in the study at any time, decline to give biological samples, and/or decline to participate in an interview. We ensure you that if you decided to no longer participate in this study, your decision will not be held against you in any kind of way.

**Potential Benefits of Taking Part in the Study.**

There are no direct benefits to you for participating in this study , but the information you provide will help us gain a better understanding of how to develop an appropriate 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 must report that information to the appropriate authorities. The consent and contact forms will be stored separately to transcripts in locked file cabinets. The South African MRC ethics committee will however have access to all data. Deidentified data will be shared with the funding body NIH and archived with NIH according to their policy.
We will use the data from the interviews to write up and publish papers in academic journals, but this data will be anonymized (we will use a participant number instead of your name). Your name will therefore not appear anywhere in any published material.

There is a small possibility that a person may gain access to the information you gave us without our permission. Every effort will be made to protect your privacy and no personal details or names will be used during the interview.

**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).

**Compensation**
While taking part in this study, you will be required to meet with study staff at the health facility once a month to provide a urine and dry blood sample that will be tested for alcohol, tobacco, cannabis and other substances. You can receive R200 for testing negative for each substance in your first month of participation in the research. Following that, your earnings will increase by R50 till the study is completed. However, if your sample tests positive for a substance, your earnings will be reduced back to R200. Additionally, you will be compensated R200 for completing screening and a baseline assessment and R300 for completing the follow-up assessment at the end of the study.

**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: petal.petersen@mrc.ac.za

Mental Health, Alcohol, Substance use and Tobacco Research Unit
Medical Research Council
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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 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)** | |

**Adapting and testing a behavioral intervention to prevent FASD and adverse infant outcomes**

**Proposal for MRC Ethics Committee**

**April 2024**


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**Key words:** pregnant, post-partum, alcohol use, tobacco/cannabis, polysubstance, breastfeeding, contingency management, educational support.

**Please note**: The research proposal is for a National Institute of Health grant to be funded by NIAAA. The proposal has been selected for funding. In keeping with the funding guidelines, after MRC ethics approval

## DECLARATION

I, Petal Petersen Williams have read the Department of Health: *Ethics in health research: principles, processes and structures, second edition*, 2015, the *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa,* Second Edition, 2006, Department of Health, Pretoria, South Africa , and the Declaration of Helsinki (2013) and have prepared this proposal with due cognisance of its content. Furthermore, I will adhere to the principles expressed when conducting this proposed research project.

11 April 2024

Petal Petersen Williams

Date

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# 1. Summary

South Africa (SA) has a long history of social and health disparities,[1–5] resulting in the world's highest rate of fetal alcohol spectrum disorder (FASD; 111.1 per 1,000),[6] where lifelong negative cognitive and physical effects result from prenatal alcohol exposure.[7–10] FASD is completely preventable if women do not drink during pregnancy.[10–12] Prenatal alcohol use frequently co-occurs with other substance use, especially tobacco and cannabis,[13–15] and cannabis use during pregnancy may increase because of cannabis legalization in SA in 2018.[16] The adverse effect on birth outcomes by alcohol and tobacco use together is worse than either substance alone.[17] Recent evidence from animal models shows that prenatal exposure to both cannabinoids and alcohol potentiate the likelihood of alcohol-induced birth defects.[18,19] Data from Cape Metropole, SA, showed that all women who reported prenatal alcohol use also tested positive for tobacco use, with 25% also reporting cannabis use. Alcohol use while breastfeeding also occurs at a relatively high rate in SA.[20–22] Despite tremendous health benefits from breastfeeding for both women and their infants,[23–40] maternal alcohol use while breastfeeding significantly compromises infant development.[20,41] Although there is strong evidence for associations between prenatal/postpartum alcohol use and FASD risk/compromised child development[11,20] as well as evidence that polysubstance use (i.e., alcohol and combined use with tobacco and cannabis [tobacco/cannabis]) during pregnancy exacerbates birth outcomes, few effective and sustainable interventions address polysubstance use (i.e., alcohol and tobacco/cannabis) during pregnancy and lactation to prevent adverse effects in women and infants.

Contingency management (CM) has been efficacious in reducing prenatal cocaine, alcohol, and tobacco use in the United States (U.S.).[42] The Women's Health CoOp (WHC) is an evidence-based brief intervention addressing women-focused syndemic issues and resulting disparities associated with substance and alcohol use.[43] These evidence-based interventions need to be combined and adapted for addressing maternal polysubstance use and associated health and behavioral issues during pregnancy and lactation. This R61/R33 is based on a partnership between researchers in the U.S. and researchers and community partners in SA to **adapt and test an evidence-based behavioral intervention to decrease polysubstance use (i.e., alcohol and tobacco/cannabis) during pregnancy and lactation and to prevent adverse clinical outcomes, including FASD.** The R61 phase will include conducting qualitative research to adapt an evidence-based behavioral intervention to the key population of women in SA and testing feasibility, acceptability, and appropriateness among women who are pregnant or breastfeeding with a recent history of polysubstance use. The intervention format will include contingent incentives on abstinence. Text-based remote support based on WHC educational components will be provided with health promotion and referral content tailored to the key population of women.[44,45] The Centers for Disease Control and Prevention (CDC) adaptation process of evidence-based interventions (i.e., ADAPT)[46] with determinants for adaptation from the Consolidated Framework for Implementation Research (CFIR)[47] will guide the adaptation process. Part of the Framework for Reporting Adaptations and Modifications-Expanded (FRAME) approach[48] will be used to document the adaptation process. The R33 phase will test the effectiveness of the adapted intervention in a randomized controlled trial on maternal

polysubstance use and gestational, birth, and infant outcomes and conduct preliminary cost-effectiveness analyses. The **Specific Aims** are as follows:

**R61 Aim 1:** To conduct formative qualitative research with women who are pregnant or breastfeeding with a recent history of polysubstance use, clinic and community stakeholders, and an established Community Collaborative Board (CCB) to inform adaptation of evidence-based interventions (i.e., CM and WHC educational components) to maternal polysubstance use during pregnancy and lactation in Cape Metropole, SA.

**R61 Aim 2:** To test feasibility, acceptability, and appropriateness of the adapted intervention with 48 women (24 who are pregnant and 24 who are breastfeeding) in SA, to help women abstain from polysubstance use during pregnancy and lactation and address disparities in polysubstance use and associated health issues.

*Milestones for assessing R61 success will include completing qualitative research for intervention adaptation and completing feasibility, acceptability, and appropriateness testing with 48 women for the R33 trial.*

**Public Health Impact.** With the effectiveness of the adapted intervention on reducing maternal polysubstance use during pregnancy and lactation and addressing and understanding disparities in the affected group of women, findings can inform providers, policymakers, and the public on the importance of targeting maternal polysubstance use with associated syndemic issues and resulting disparities for sustainable implementation in treatment settings (e.g., substance use treatment clinics, obstetric clinics, and community programs for mothers/children) in SA, U.S., and other countries.

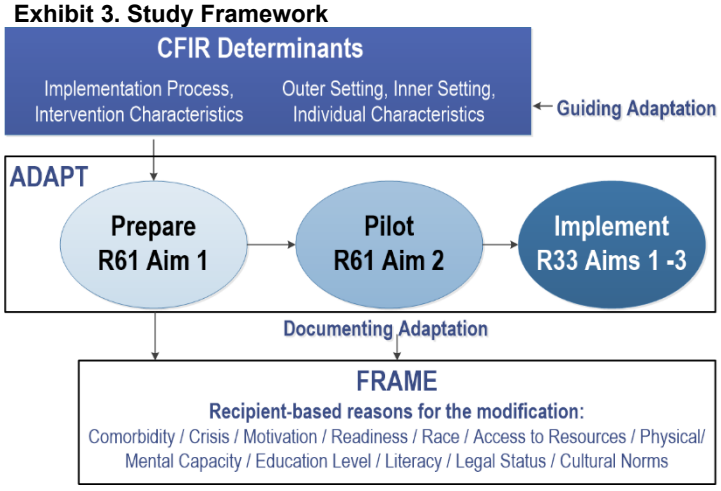
***The current ethics application is for R61 Aim 2 only***

# 2. Research Strategy

## 2.3 Approach

***2.3.1 Study overview and scientific design.*** The CDC adaptation process of evidence-based interventions (i.e., ADAPT)[46] will guide the adaptation process. ADAPT has 5 steps of Assess, Select, Prepare, Pilot, and Implement. Our study team has successfully used this rigorous CDC adaptation framework in prior adaptations of WHC and other evidence-based interventions.[137,138] The proposed study will focus on the last 3 steps. The R61 phase will last 2 years and will be spent conducting qualitative research (Aim 1) and testing feasibility, acceptability, and appropriateness of the adapted intervention to reduce maternal polysubstance use during pregnancy and lactation in SA (Aim 2) as the Prepare and Pilot steps of ADAPT. The R33 phase will encompass the Implement step of ADAPT by testing the effectiveness of the adapted intervention. Determinants for adaptation used in the proposed study will be those from CFIR.[47] We will use the FRAME approach[48] to document the adaptation process, specifically focusing on the recipient-based reasons

**Exhibit 3. Study Framework**



for the modification during the R61 phase (**Exhibit 3**), such as issues specific to stigma and maternal alcohol and combined use with tobacco/cannabis that have not been studied.

***2.3.4 Community Collaborative Board (CCB).*** A Cape Town CCB was established by Dr. Wechsberg in 2003 and remains active 18 years later. The CCB includes members from substance use treatment clinics, maternal/infant health providers, health department officials, nongovernmental organizations, and university researchers involved in NIH studies. The CCB will meet initially using a virtual platform (e.g., Zoom) to learn about the study design, goals, and formative plans and materials. The CCB will meet at least twice a year throughout the life of the project. The CCB also will review the proposed intervention materials, offer ongoing feedback about the study (e.g., recruitment and retention), identify relevant stakeholders, and assist with dissemination.

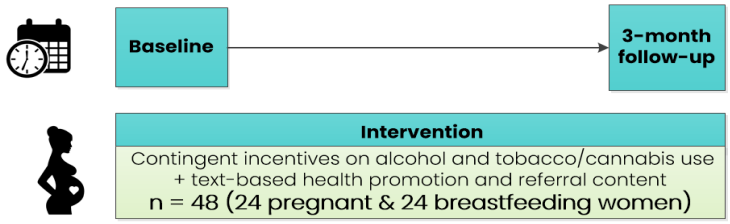
***2.3.5 Study timeline (R61 phase: Months 1–16).*** The R61 timeline is described in **Exhibit 4**.

**Exhibit 4. Proposed Study Process (R61 aim 2: Months 1–16)**

| Aim 2: Feasibility, Acceptability, and Appropriateness Testing Phase | |
|---|---|
| **Months 1-6** | **Months 7-16** |
| ▪ Train staff<br>▪ Feasibility, acceptability, appropriateness testing and instrumentation<br>▪ 3-month follow-up assessments and interviews<br>▪ Ongoing DSMB<br>▪ Ongoing CCB | ▪ Modifications of the tested intervention<br>▪ Complete data cleaning and analyses<br>▪ Prepare for the R33 phase<br>▪ Ongoing DSMB<br>▪ Ongoing CCB |

***2.3.7 R61 Aim 2: To test feasibility, acceptability, and appropriateness of the adapted intervention with 48 women (24 who are pregnant and 24 who are breastfeeding) in Cape Metropole, SA, to help women abstain from polysubstance use (i.e., alcohol and tobacco/cannabis) during pregnancy and lactation.***

**Exhibit 5 Feasibility, Acceptability, and Appropriateness Testing**




The R61 Aim 2 will focus on testing the feasibility, acceptability, and appropriateness of the adapted intervention with 48 women (24 pregnant and 24 breastfeeding). This testing will occur for 3 months with a follow-up assessment and interview at the end (**Exhibit 5**). The R61 Aim 2 will consist of the Pilot step of ADAPT and will collect and document information on barriers and facilitators from participants based on the recipient-based reasons of FRAME.[48]

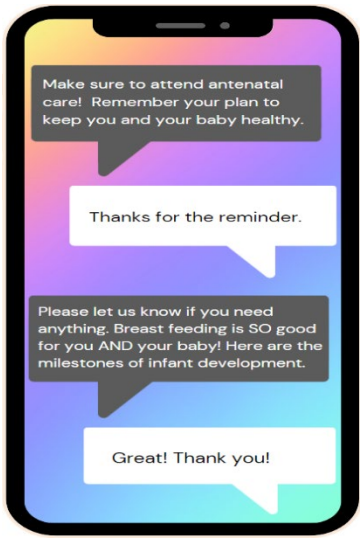
**Eligibility.** To be eligible, women must (1) be in the second trimester of pregnancy or breastfeeding with less than 3 months postpartum, (2) test positive in alcohol use by urinalysis (i.e., EtG), (3) test positive in tobacco or cannabis use by urinalysis (i.e., cotinine and THC), (4) be over 18 years old, (5) have a negative HIV test, (6) not be eligible for PrEP, (7) plan to complete antenatal care at the current clinic and remain in the area for at

least 3 months, and (8) own a cell phone to receive text messages. Exclusion criteria include women who report serious medical problems threatening their current pregnancy or current suicidal thoughts or attempts in the past month. These women will be provided necessary referrals. Women who participated in interviews during Aim 1 will not be eligible. We will recruit 48 participants (24 pregnant and 24 breastfeeding) over 3 months, with at least 16 participants per month. **Recruitment.** Research staff will deliver study posters and flyers to clinic staff so they can display them at each site. Research staff in the waiting area of the clinic will approach women and introduce the study. Additionally, clinic staff routinely ask about prenatal alcohol and substance use; therefore, clinic staff will also refer women who self-report prenatal alcohol and tobacco/cannabis use to research staff. We will ensure all COVID-19 safety protocols are followed, maintain 1.5 meters distance, and make use of personal protective equipment where necessary. Research staff also will provide a sign-up sheet to fill in their first name and contact number for making screening appointments during clinic visits. This recruitment procedure has been the standard for recruiting maternal populations in substance misuse and mental health studies in community clinics in SA.[62,165]

To recruit women who are less than 1 month postpartum, research staff will approach women at an MOU clinic who are more than 35 gestational weeks and intend to breastfeed and will contact interested women after their due date to confirm their breastfeeding status and study interest and make a screening appointment at a Baby Clinic following their postpartum appointment. Research staff will also approach women at a Baby Clinic who are less than 1 month postpartum and breastfeeding and ask their interest in the study. Interested women will be screened in person following consenting in a private room at either an MOU or Baby Clinic. Following consent, we will collect detailed contact information and begin screening and baseline assessment in either English, Afrikaans or isiXhosa, if eligible. We will follow all COVID-19 safety protocols.

**Screening and baseline appointment.** Pre-screening consent **(Appendix 1)** will be obtained in order to collect biological samples for screening. Screening **(Appendix 2)** will occur immediately followed by consent **(Appendix 3)** at a clinic for those who screen positive and are interested in participation. For eligible participants a contact information form will be completed fr future follow up (Appendix 4). Baseline assessment **(Appendix 5)** will occur immediately following screening at the clinic. Interview questions will be conducted by CASI on a tablet. Assessment questions will cover sociodemographic factors; social determinants; recent and lifetime polysubstance use; IPV/GBV exposure; partner drinking; stigma; coping with stress; and reproductive, sexual, physical, and mental health. Urine samples collected during screening will be used to test other substance and Mandrax use. Participants will be asked to provide a few drops of blood (more or less 5 drops/ 1 teaspoon) by piercing the skin of the finger with a small needle. The blood drops will be dropped on a dried blood spot (DBS) card to be tested for recent alcohol use with the Phosphatidylethanol (PEth) test. All pricks will be performed by staff who are fully trained in blood sample collection, samples will be marked with the unique participant number. At the end of each day, these specimens will be transported to the SAMRC site. The blood samples will only be identified by the unique participant number and

**Exhibit 6. Text-based support**



will not be linked to any personally identifiable information. DBS cards will be stored in a cool dry place at the SAMRC site until ready for transportation to the USA for testing. Each screening and baseline assessment will take approximately 1 hour. Participants who complete both screening and baseline assessments will be thanked for their participation and receive R200.

**Proposed intervention.** Findings from the formative qualitative phase highlight the need for an intervention programme that is innovative and tailored to the needs of women who are pregnant or postpartum. It highlights the importance of developing intervention programmes that move beyond education about the harms of drinking in pregnancy to include people's attitudes towards drinking in pregnancy. It highlights the need to provide education around the harms associated with substance use in breastfeeding. There is a need to focus on the social norms around substance use and the normalisation of drinking, smoking and cannabis use among perinatal women. It also highlights the importance of including community-based support, support groups, counselling, partner involvement and having a committed research team offering further support in these interventions. Findings also suggest there is a lot of support for the provision of contingent incentives. While most support the provision of cash incentives, some mentioned providing food parcels. Participants will receive text-based support using basic language on health promotion and referral content based on WHC educational components (**Exhibit 6**). Messaging content and format details have been determined with qualitative research findings in Aim 1; however, the content will stay relatively generic so that study involvement is not clear to others who may accidentally view the messages. Aim 1 findings revealed that perinatal women would value messages of encouragement and reminders to eat well and drink water. Health workers throught messages should inlcude what danger signs to look out for that may indicate high risk and a reason to go see a healthcare provider. Participants will be asked to meet research staff on a monthly basis at the clinic to provide a urine sample, fill out timeline follow back on self-reported alcohol and tobacco/cannabis use, and receive contingent incentives if abstinence is verified. R200 will be provided per biochemically verified EtG abstinence for alcohol use,[98] R200 per biochemically verified cotinine abstinence[105] for tobacco use, and R200 per biochemically verified THC[103] for cannabis use (**Exhibit 7**). Biochemically verified abstinence in subsequent months will increase the incentive magnitude by R50 monthly for each substance. Total potential earning for 3 months will be R1,500 to R2,250 depending on whether a participant uses alcohol and tobacco or alcohol, tobacco, and cannabis together. If a participant provided a positive sample, the incentive goes back to R200.

**Exhibit 7. Contingent Incentives**

| Timing | Amount for abstinence per drug (EtG, cotinine, THC) | Total potential earnings |
|---|---|---|
| **Month 1** | R200 each | R400–R600 |
| **Month 2** | R250 each | R500–R750 |
| **Month 3** | R300 each | R600–R900 |

**Follow-up assessment.** Participants will be asked to participate in the 3-month follow-up assessment at a clinic at the end of the 3-month testing. Assessment questions **(Appendix 6)** will be conducted via CASI on a tablet covering recent self-reported alcohol and tobacco/cannabis use; self-reported use of other substances; recent IPV/GBV exposure; partner drinking; stigma, stress; and reproductive, sexual, mental, and physical health (see **Measures**). Consent will be obtained **(Appendix 7a)** to collect participants' birthing facility information for those who were recruited during pregnancy to track birth outcomes **(Appendix 7b)**. If a participant is already postpartum and breastfeeding, self-reported

incidents of breastfeeding while using alcohol and tobacco/cannabis will be collected. Infants will also be measured for their height, weight, and head circumference. Participants will be also asked to provide a blood sample. Urine samples collected at the 3rd monthly visit will be used to test other substance and Mandrax use. (See Appendix 8 and 9 for biological collection forms). An assessment and the subsequent interview will take approximately 90 minutes. Participants will be thanked for their participation and compensated R300 for their time. Participants who experience an adverse outcome prior to follow up such as miscarriage, stillbirth or decide to discontinue will not be replaced.

**Measures.** Proposed measures are below in **Exhibit 8**, which includes all phases (color-coded by aims).

| **Primary Outcomes (R61 Aim2 & R33 Aim1)** | **Data Source(s)** | **Visit/Time** |
|---|---|---|
| **Urinalysis results for alcohol use:** An alcohol metabolite (EtG) will be measured in urine samples.[168] EtG can be detected in the urine up to 5 days after heavy drinking and up to 2 days after light drinking with ≥150 ng/mL for EtG as a cutoff value.[169] The dipstick testing will have ≥300 ng/mL as a cutoff value.[170] | Dipstick (CONFIRM BIOSCIENCES); EtG ELISA (Microgenics Corp) | Screening & Baseline (BL); Follow-ups (FUs) |
| **Urinalysis results for tobacco use:** Biochemical verification of recent tobacco use in urine samples. A tobacco metabolite (cotinine) will be measured in urine samples.[171] The metabolite can be detected up to 3–4 days after use with ≥ 80ng/mL as a cutoff value.[172] The dipstick testing will have ≥200 ng/mL as a cutoff value.[170] | Dipstick (CONFIRM BIOSCIENCES); Cotinine ELISA (Abnova) | BL; FUs |
| **Urinalysis results for cannabis use:** Biochemical verification of recent cannabis use in urine samples. A cannabis metabolite (*THC*) will be measured in urine samples.[173] The metabolite can be detected up to 28 days after heavy use with ≥50 ng/mL as a cutoff value.[174] The dipstick testing will have ≥50 ng/mL as a cutoff value.[170] | Dipstick (CONFIRM BIOSCIENCES); THC ELISA (Sigma-Aldrich) | BL; FUs |
| **Blood analyses for alcohol use:** An alcohol metabolite (PEth) in blood samples will be measured as a gold standard biomarker of past 30-day alcohol consumption. The cutoff level of ≥50 µg/L indicates heavy drinking.[175] | Gas chromatography | FUs |
| **Self-reported alcohol use:** Self-reported daily alcohol use by the number of standard drinks based on the definition in South Africa (e.g., 12 g per standard drink). | Timeline follow-back/recall (TLFB) | BL; FUs |
| **Self-reported tobacco/cannabis use:** Self-reported use of daily cannabis by the number of cones/joints/pipes[176] and of daily tobacco by the number of puffs (8 puffs = 1 cigarette).[105,177] | TLFB | BL; FUs |
| **Self-reported alcohol and tobacco/cannabis use while breastfeeding:** Self-reported incidences of alcohol and tobacco/cannabis use while breastfeeding noted in a daily log. | TLFB | FUs |
| **Secondary Outcomes (R61 Aim2 & R33 Aim2)** | | |
| **Gestational & birth outcomes:** Gestational hypertension, gestational diabetes, preeclampsia, other gestational complications; Weight, height, head circumference, gestational age, NICU admission, length of stay, Apgar scores, etc. | Medical record | At Birth |
| **Infant outcomes:** Infant weight, infant height, head circumference, outpatient and inpatient medical visits. | medical records; | Postpartum FU only |
| **Other Relevant Measures (R61 Aim2 & R33 Aim1)** | | |
| **Urinalyses results for substance use:** Urine metabolites of recent drug use 5-drug panel + Mandrax strip. | Dipstick (CONFIRM BIOSCIENCES) | BL; FUs |
| **Self-reported substance use:** Self-reported use of illicit substance use in type, frequency, and severity. Alcohol, Smoking and Substance Use Involvement Scale (ASSIST). | ASSIST[178,179] | BL; FUs |
| **IPV/GBV:** Lifetime and recent (past 3 months) main partner emotional, physical, sexual, and financial abuse. At baseline, family violence and past experience with abuse (e.g., age of onset). | Revised Risk Behavior Assessment (RRBA)[180] | BL; FUs |
| **Partner drinking:** Partner drinking in the prior month and perceived problematic drinking. | RRBA[180] | BL; FUs |
| **Stigma:** Everyday discrimination scale (EDS) will be used to measure perceived stigma. | EDS[181] | BL; FUs |
| **Coping:** Brief Resilience Scale (BRS) will be used to measure coping with stressors. | BRS[182] | BL; FUs |
| **COVID-19−related issues:** Knowledge, attitude, and impact of COVID-19 on stigma,[183] mental health, employment, housing, family and partner relationship, and social network. | Newly developed | BL; FUs |
| **Reproductive and sexual health**: Contraceptive use and sexual risk behavior (e.g., condomless sex, alcohol and other drug use prior to or during sex, casual and concurrent partners, and sex trading). | RRBA[180] | BL; FUs |
| **Psychological distress/depression**: Patient Health Questionnaire-2 (PHQ-2); Generalized Anxiety Disorder (GAD-2); Edinburgh Postnatal Depression Scale (EPDS; alpha=0.91). | PHQ-2[184]; GAD-2[185]; EPDS[186] | BL; FUs |
| **Participant Characteristics (R61 Aim2 & R33 Aim1)** | | |
| **Social determinants:** Age, race, family structure, education, marginal housing & instability conditions, partner age, mobility, economic status, food insecurity. | RRBA[180] | BL |
| **Alcohol and substance use problems**: Lifetime use, age at first use, Substance Use Risk Profile-Pregnancy (SURP-P), Drug Abuse Screening Test (DAST). | RRBA[180]; SURP-P[187]; DAST[188] | BL |
| **Nicotine use problems:** Lifetime use, age at first use, Level of nicotine dependence (Fagerstrom) | RRBA[180]; Fagerstrom[189] | BL |
| **Relationship equity & Sexual control:** A 10-item subscale of the Sexual Relationship Power Scale (SRPS) assessing decisional influence. Six items assessing influence in sexual decisions. | SRPS[190] | BL |
| **Implementation Related Measures (R61 Aim2)** | | |
| **Feasibility:** Feasibility of Intervention Measure (FIM). | FIM[191] | Interview |
| **Acceptability:** Acceptability of Intervention Measure (AIM). | AIM[191] | Interview |
| **Appropriateness:** Intervention Appropriateness Measure (IAM). | IAM[191] | Interview |
| **Intervention Satisfaction:** Assesses satisfaction through questions that ask about their experience. | Satisfaction Form | Interview |

| Cost Related Measures (R33 Aim3) | | |
|---|---|---|
| **Healthcare utilization & patient costs:** Adapted Economic Form (AEF) 90—participants' other healthcare utilization, resources spent, out-of-pocket expenses. | AEF 90[192] | BL; FUs |

**Data management.** All data will be entered into REDCap™, which will have built-in checks for consistency and completeness. Electronic data entered in REDCap™ will be downloaded to the internal RTI project share nightly. All data, including forms with personally identifiable information (locator and consent forms), are kept on password-protected servers. Dr. Washio will be responsible for reviewing and cleaning the data and preparing weekly reports during data collection, with guidance from other investigators.

**Staff communication and quality assurance.** Two female field staff members who speak the local languages (isiXhosa and Afrikaans) besides English will be hired by SAMRC and extensively trained and monitored by the PI and site PIs. Staff will recruit participants, conduct baseline assessments, and manage the database. Dr. Petersen Williams will communicate with research staff to supervise day-to-day operations. Dr. Washio will be available to communicate with Dr. Petersen Williams on a daily basis by email, Zoom, or Skype. Dr. Washio will also establish an effective communication plan between investigators, consultants, staff, and CCB members, including weekly conference calls, email distribution lists, and end-of-day reports. Quality assurance systems will be put in place to generate daily reports, perform data entry, undertake quality assurance checks, and ensure that data are cleaned and accurately transmitted, organized, and properly managed. With permission, Dr. Petersen Williams will observe 20% of baseline and follow-up appointments as well as monthly intervention sessions to monitor fidelity on intervention components and delivery manners.

**Power analysis.** A sample size of 48 will achieve 80% power for 20% decreases in alcohol and tobacco/cannabis use from baseline to 3-month follow-up. **Hypothesis.** We hypothesize to detect a rate of >80% of the average full score per participant based on the 5-Likert scales in FIM, AIM, and IAM measures and 20% decreases in alcohol and tobacco/cannabis use from baseline to 3-month follow-up. **Consideration of sex and other biological variables.** Evidence shows that women are more adversely affected than men by drinking with susceptibility to craving and relapse.[193] The proposed study is enrolling female participants; thus, no sex differences will be examined. However, differences by age will be examined. **Data cleaning and missing values.** All data will be reviewed for valid values/data entry errors, outliers, and the extent and pattern of missing data. Consistency and logic checks that constitute standard review/cleaning procedures will be applied. We will use the mean substitution for continuous values and mode for categorical values, last observation carried forward, and expectation-maximization to handle missing values, depending on the features of missingness. If necessary, we will use the multiple imputation procedure to treat missing values by creating multiple datasets with imputed values.[194] Sensitivity analysis will be conducted to evaluate the robustness of the results with the deviations from the missing at random assumption.

**Data analysis.** Descriptive statistics will be used to summarize both continuous (via means, standard deviations, and medians) and categorical (via proportions and total numbers) variables for the outcomes. The acceptability and appropriateness outcomes will be AIM and IAM scores. Two feasibility outcomes exist: FIM scores and polysubstance abstinence. Maternal polysubstance use measures include urinalysis dichotomous results and self-reported use during pregnancy and lactation. Dichotomous outcomes of 7-day point-prevalent abstinence of alcohol, tobacco, and cannabis will be calculated for baseline and 3-month follow-up timepoints

by combining urinalysis results and self-reported use during the past week before each assessment. If both urinalysis and self-reported results are negative, the dichotomous outcome will be coded as negative of use and otherwise coded as positive of use. We will also summarize urinalysis results and self-reported use separately for each substance in each month. We will also apply the same summary procedure for polysubstance abstinence, in which case an incident of urinalysis and self-reported results for alcohol and tobacco/cannabis showing negative will be coded as negative of use, and an incident of either substance showing positive in either measure will be coded as positive of use. Again, we will also summarize urinalysis results and self-reported use separately for polysubstance use in each month. Self-reported use provides continuous use outcomes; thus, we will calculate the average with standard deviations and median per day, week, or month and the overall number of days used. Secondary feasibility outcomes are gestational, birth, and infant outcomes. Gestational and birth outcomes among participants will be compared with the national average and also the average in a similar cohort of SA women (**Exhibit 1**). Changes in infant outcomes from baseline to 3-month follow-up will be compared to reduction in polysubstance and singular substance use to examine dose-dependent correlations. Participant characteristics, social determinants, and other relevant measures (see **Measures**) will be collected so that we can conduct the variable selection method to identify and rank the most influential covariates for moderator and mediation analyses in the R33 phase. Trend analyses will be conducted to statistically evaluate the features of changes from baseline in some of the variables to follow-up assessments. Analyses will be stratified by pregnnacy/lactating status.

*Milestones for assessing R61 success will include completing qualitative research for intervention adaptation and completing feasibility, acceptability, and appropriateness testing with 48 women for the R33 trial.*

R33 AIM 1-3

Ethics approval will be sought following completion of R61 Aim 2 to ensure findings from R61 Aim 1 and 2 are incorporated into R33.

# 3. Ethical Considerations

### *Human Subjects Population*

The proposed study population primarily comprises women who are pregnant or breastfeeding with a recent history of polysubstance use and clinic and community stakeholders in SA. Furthermore, we expect that the sample will be individuals of African descent (i.e., Black African and Coloured, racial categories that were delineated during the Apartheid Era in SA).

For the feasibility, acceptability, and appropriateness testing, 48 eligible women (24 pregnant and 24 breastfeeding) will be recruited.

***Potential Risks***

Although the proposed study presents no greater than minimal risk to participants, adequate provisions will be put in place to mitigate these risks. The potential risks to participants include (1) lack of comprehension and acknowledgement of informed consent, study purpose, and rights of participants; (2) exposure to psychological or physical coercion by clinical staff and others; (3) possible disclosure of confidential information; (4) the possible mental discomfort associated with some of the sensitive issues raised during assessments and biological specimen collection and results; and (5) social ramifications of participation in the study. These scenarios and the steps to mitigate the risks are detailed under **3.1.2 Adequacy of Protection Against Risks** below.

## Adequacy of Protection Against Risks

### *Recruitment and Informed Consent*

**Recruitment.** Participation in the study is voluntary. Trained research staff will ask for permission from facility management to post and display study posters at each MOU study site. Research staff will market the study and recruit women in the waiting area of the clinic and introduce the study. Clinic staff will also refer potential participants to the research staff if participants are interested in joining the study. Research staff will use established marketing methods proven successful in our previous SA studies, which include posting marketing flyers in study clinics.

**Consent.** Before engaging in study activities, all potential participants who are interested in the study will undergo consenting procedures to provide informed consent. Consent forms will include details of study participation and activities. The form will be read to all potential participants, and they will be given the opportunity to ask questions and have them answered. Additionally, potential participants will be asked to both electronically initial and sign their written consents via REDCap. Consent forms will include the following:

A statement describing the extent to which confidentiality will be kept and how privacy of the participants will be maintained, including that the only exceptions to confidentiality will be information related to medical emergencies, participant disclosure of current child/elder/dependent abuse or neglect, and imminent risk of death or serious injury to the participant or others;

A statement that participation is voluntary;

A statement that research data and their involvement or early termination in the study will not affect their access to any services, including treatment;

An explanation of who to contact for answers to pertinent questions about the research and research participants' rights; and

Who to contact for a research-related adverse situation, such as an injury.

Finally, potential participants will be informed of all known potential risks and benefits of participation, their right to refuse or revoke consent at any time, and the names and phone numbers of responsible individuals they may contact for additional information or to register complaints about study procedures. Consented participants will be given a hard or soft copy of their signed consent form for their own personal records. Women who decline participation in the study will not receive differential treatment at clinics, and no information collected

during research participation will be shared with clinic staff. Individuals who do not provide written consent for the study will not be screened. Participants will be reminded that they have the right to discontinue participation in the study at any point and to refuse to answer any specific questions or let staff collect biological samples if they choose. They will also be told about the possibility in consenting for future studies.

**Screening.** All interested individuals who provided written and verbal consent will be screened to determine eligibility. Screening will occur individually and privately. Ineligible women will not be told the reason for their ineligibility. Those who screen eligible will be enrolled in the study. Those who are ineligible because of reporting serious medical problems threatening their current pregnancy or current suicidal thoughts or attempts in the past month will be given necessary referrals. If a participant is not eligible, she will be thanked for her participation in screening and receive 50 South African Rand via a mobile cash-send mechanism.

**Confidentiality.** Drs. Washio and Petersen Williams will be responsible for training the staff on all protocols to ensure confidentiality and protocol fidelity. Each field staff member will follow prescribed guidelines and regulations when screening potential participants. This will be scripted in the Operations Field Manual. All field staff will review regulations regarding confidentiality and signed agreements will be kept on file. The exceptions to these regulations include threats of imminent harm (to self or others) or ongoing abuse or neglect of children. All proposed project staff will complete the Collaborative Institutional Training Initiative (CITI) training course or a comparable course on the roles and responsibilities in protecting the privacy and confidentiality of research participants.

### *Protections Against Risk*

This project will adhere strictly to SA ethics and regulations for the protection of human subjects and follow best-practice procedures for ensuring data security.

#### *Protections Against Risk Associated with Informed Consent*

Before proceeding with the study procedures, individuals will be fully informed about the purpose of the study and study procedures. During the consenting process, a trained project staff member will describe the purpose and goals of the study, investigator and participant responsibilities, and the study procedures. During this description, all expectations of participants, the voluntary nature of participation, and rights to confidentiality will be emphasized. It will be made clear that participation in this study is voluntary and that individuals can refuse to participate, agree to participate and then withdraw their consent, or participate until completion of the study. Potential participants will be informed of the names and phone numbers of responsible individuals that they may contact for additional information or to register complaints about the study procedures. They will be given an accurate and fair description of the risks or discomforts and the anticipated benefits of the research study, as outlined in the International Conference on Harmonization–Good Clinical Practice (ICH-GCP) guidelines and the South African guidelines for Good Clinical Practice, so they can make an informed decision about participation. Potential participants will be asked to repeat in their own words what is expected of them and their rights as a study participant.

***Protections to Mitigate Participants' Exposure to Psychological or Physical Coercion by Clinical Staff and Others***

If research staff detect psychological and physical coercion through direct and indirect observations during the recruitment process, they will remind women that it is their choice to be in the study and that research staff will not disclose their status of study participation to anyone. Research staff will be trained on how to handle potential coercion by clinical staff and others and will be supervised by investigators. Research staff will also have ongoing meetings with clinic staff to discuss the study/clinic expectations and issues related to the partnership.

***Protections Against Possible Disclosure of Confidential Information***

A breach of confidentiality could include unauthorized persons accessing information contained in their study files. Every effort will be made to protect the confidentiality of participant information. We will adhere to all applicable confidentiality regulations in SA. We have carefully considered the potential risks for each of the proposed research activities and have developed measures to mitigate these risks, which we have used in previous studies. These measures include staff training and data management procedures that separate identifying information from interview data.

All participants will be informed of all anticipated risks before they can consent to participate in screening for the study. During the consenting process, participants will be assured that all data collected during the study will be kept strictly confidential to the full extent provided by law. The only exceptions to confidentiality, which will be clearly explained and specified in the informed consent forms, will be for information that needs to be released to manage medical emergencies, risk of harm to self (e.g., risk of suicide), or risk of harm to others, including the abuse or neglect of a minor. The consent forms will also state that individuals will be able to refuse to participate or withdraw consent to participate at any point in time without experiencing negative consequences. Potential participants will be given opportunities to ask questions about study participation, and the research staff seeking consent will answer these questions. Individuals who do not understand the nature of the study and cannot clearly provide consent will not be able to participate in the study.

Data confidentiality will be also ensured through the study team's rigorous standardized procedures. All study staff have intensive training in human subjects' protection, GCP, and study-specific participant confidentiality procedures. They will be informed about the sanctions associated with breaching participant confidentiality and will be required to sign a staff confidentiality agreement as part of their conditions of employment. RTI, SAMRC, and UCT have a research integrity policy to which all staff must adhere. Consequences for breaching participant confidentiality include dismissal and legal sanctions. The limits to confidentiality, the possibility of data being seen by study monitors, and future sharing of de-identified data are all fully explained in the study information and informed consent forms.

Most of the data associated with the study will be entered directly by research staff into REDCap, a secured web-based data entry system that is specifically geared to support online and offline data capture for research studies and operations. REDCap is in compliance with 21 Code of Federal Regulations (CFR) Part 11,

FISMA, HIPAA, and the General Data Protection Regulation (GDPR). Tablets used for data collection will also be password protected.

There is also a risk that participants may lose their phones or may leave them unprotected so that others may gain access to its contents. This risk is minimized because only generic text messages will be sent to participants phones with no study-specific information that reveals study participation to others.

Furthermore, participants' confidentiality will be ensured at recruitment, data entry, storage, retrieval, and analysis stages. Data and any information collected from participants during the study activities will be linked to participants through a unique study ID, which will ensure anonymity. Informed consent forms, which include personal identifying information such as full names, will be printed and then stored in double-locked cabinets in a locked and secured data storage room at the SAMRC site with restricted access separate from documents with participant data and participant IDs. Any study materials will be secured in separate double-locked file cabinets in a locked and secured data storage room at the SAMRC and secured on password-protected microcomputers with the latest Windows operating system and a secure (password-protected) file server at the SAMRC or UCT site.

Biological samples, linked to participants only through unique study ID, will be transported by research staff from the study site to SAMRC site in locked briefcases. Results of the biological analysis will also be identified using the participants' unique study ID. Anyone handling these biological specimens will sign a staff confidentiality agreement.

Staff will follow strict protocols for ensuring participant confidentiality. For the interviews, project staff will confirm that each participant is in a private place. Phone interviews for clinic and community stakeholders will also be protected by staff conducting phone interviews in a private place.

Finally, there is risk to client confidentiality when research staff collect these data at an MOU. Should any breaches of participant confidentiality occur during the study, they will be reported to Dr. Washio, SAMRC's Human Research Ethics Committee (HREC), the IRB of record, the chair of the DSMB, and NIH officials.

***Protections Against the Possible Mental Discomfort Associated with Sensitive Issues Raised***

Because of the sensitive nature of some of the topics being addressed during the proposed project, participants may experience psychological or mental discomfort related to particular issues or during certain study activities, such as discussing certain topics in interviews and assessments. To reduce the risk of discomfort that may arise during study activities, participants will be informed of potential discomforts before signing the consent form and will be allowed to refuse to answer any question without penalty. Research staff will be trained on how to address discomfort among participants and how to ask research questions in a non-invasive, non-stigmatizing manner. We will establish standard operating procedures for handling distressed respondents, including determining the severity of the distress, making referrals accordingly (passive or active), and mandatory reporting procedures, based on our previous experience in SA. All study staff will be trained on these procedures. Participants will be referred to counseling if necessary or if requested.

***Procedures to Address Social Ramifications of Participation in the Study***

Participants also face stigma if others in their community find out that they are participating in a health study or that they are using alcohol and other substances while pregnant or breastfeeding. If participants experience any adverse reactions to any aspects of the study, research staff will fill out an incident report immediately, and the team will contact Drs. Washio and Petersen Williams. Using advice from senior project staff, the field staff will make appropriate referrals to medical, counseling, or other health services. Dr. Washio will report serious adverse events, adverse events, and unanticipated events within 48 hours (24 hours for fatal events) to the NIAAA Program Officer, the SAMRC HREC, and the Chair of the DSMB. Serious adverse events, adverse events, and unintended events are further discussed in the **Data and Safety Monitoring Plan.**

*Adverse Events (AEs) and Serious Adverse Events (SAEs).*

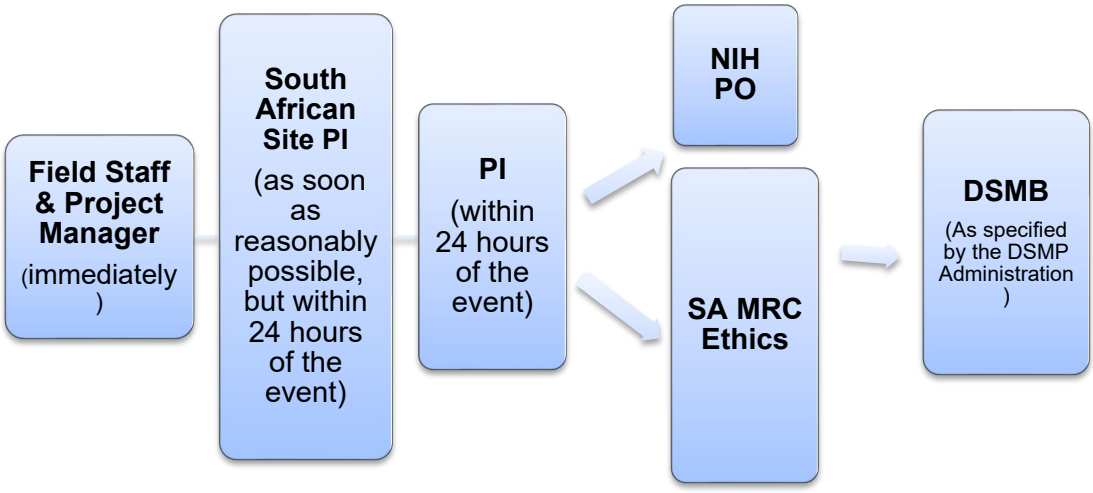
*Adverse Events (AEs)* will be defined as: report of coercion to participate in the study; or significant hesitance, concern or emotional distress from answering research questions, such that the participant decides to stop their participation; and harm resulting from breach of confidentiality. Medical events for pregnancy-related and postpartum health, psychiatric issues including suicidal ideation, or substance abuse that do not require urgent medical attention, emergency care, and/or hospitalization will be also treated as AEs. We will monitor attrition rates for participants, but dropout from the study will not be reported as an AE unless it is related to an untoward event from study participation. Participants may have medical and psychiatric problems before entering the study, which may continue during the course of the study. As per the definition of AEs, only significant worsening of baseline medical or psychiatric status or new problems will be reported as AEs. The AEs listed above have been known to occur in prior research with the target population. However, due to the protections we have put in place we do not anticipate report of coercion to participate in the study; significant discomfort from answering research questions; or harm resulting from breach of confidentiality occurring. We do not anticipate pregnancy-related and postpartum health, psychiatric issues including suicidal ideation, or substance abuse occurring as a result of the study procedure.

*Serious Adverse Events (SAEs)* will be defined as maternal or neonatal death; or any life threatening event that requires urgent medical attention, emergency care, and/or hospitalization including prenatal and postpartum health issues, psychiatric issues, and substance use or social harm for participating in the study and their partners knowing about it; however, No SAEs are expected as a result of the study procedures or intervention. If an SAE is identified, then staff members are instructed to learn the details of the AE and complete an internal study-specific AE form and immediately forward this form to the PI. AEs will be labeled according to severity, which is based on their impact on the patient. An AE will be termed “mild” if it does not have a major impact on the patient, “moderate” if it causes the patient some minor inconvenience, and “severe” if it causes a substantial disruption to the patient’s well-being. A severe AE and an SAE are distinct terms. A subject could experience a severe AE that does not meet the above-listed definition of an SAE; alternatively, a subject could experience a moderate AE that meets the SAE definition. AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled as definitely unrelated, definitely related, probably related, or possibly related to the study intervention. All AEs and SAEs occurring during the study are

documented on a form, reviewed and signed by the PI, and reported to IRB of record. Determination of protocol relatedness is made by the PI after consultation with other investigators and research staff. This initial determination is reviewed, and a final determination is made by the IRB of record. All non-fatal SAEs are reported to the IRB of record within 48 hours of our awareness of the event (24 hours for fatal events).

All reporting will follow the expectations and timeframes specified in the current NIH guidelines for reporting (see **Figure 1**). This includes reporting a summary of all AEs and/or SAEs that are deemed expected and/or unrelated to the study to the PO with the annual progress report. In the event that a participant either withdraws from the study, or the PI decide to discontinue a participant due to an SAE, the participant will be monitored by the investigator via ongoing status assessment until (1) a resolution is reached (the problem requiring hospitalization has resolved or stabilized with no further changes expected), (2) the SAE is determined to be clearly unrelated to the study intervention, or (3) the SAE results in death. Annual summaries of the SAEs that occurred during the previous year will be included in the yearly progress report to the IRB. This summary will be in the form of a table that shows each type of AE and an overall summary of the SAEs. Unexpected adverse events will be reported in accordance with NIH and Federal Requirements as well as requirements from the South African Department of Health's Research Committee.

Figure 1. Reporting Flow




***IRB Assurances***

Before implementing the study protocol, we will obtain human subjects' approval of this research protocol from the IRB with a reliance agreement signed by other relevant institutions. Given the relatively low risk associated with participating in this study and the safeguards we have in place for these potential risks, we anticipate that we will successfully obtain IRB approval.

Additionally, it is important to note that after providing informed consent, participants will be assigned a study identification number that will be affixed to all collected data. Linkage between participant identity and identification numbers will be stored in a locked, secure location or in a password-protected computer spreadsheet that will be available only to the investigators and other relevant research staff. This linking file will be destroyed 3 years after the end of the study.

### *Vulnerable Subjects*

#### *Pregnant Women, Fetuses, and Neonates or Children*

This research proposes voluntary involvement of women who are pregnant and infants, in compliance with *Subpart A:Section 56.204 (82 FR 7259, 7273, Jan. 19, 2017) of Basic U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects,* in that (a) there is no risk to the fetus associated with this proposed research, (b) this study will provide data for assessing potential risks associated with alcohol and other substance use to women who are pregnant and fetuses and infants, (c) the research holds the prospect of a direct benefit both to women who are pregnant and fetuses and infants, and (d) a woman's consent is obtained in accordance with the informed consent provisions of Subpart A—including that she is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; no inducements, monetary or otherwise, will be offered to terminate a pregnancy; individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and individuals engaged in the research will have no part in determining the viability of a neonate.

It is important to note that women who are pregnant will only participate in interview questionnaires.

## Potential Benefits of the Research to Research Participants and Others

We believe that the aforementioned risks are reasonable in relation to the anticipated benefits from collecting information on feasibility, acceptability, appropriateness, and effectiveness of the adapted intervention to reduce maternal polysubstance use during pregnancy and lactation in SA. We believe the new scientific information to be gained in the proposed study outweighs the risks involved.

## Importance of the Knowledge to be Gained

SA has a long history of social and health disparities, and resulting in the world's highest rate of FASD (111.1 per 1,000), where lifelong negative cognitive and physical effects result from prenatal alcohol exposure. The adverse effect on birth outcomes by alcohol and tobacco use together is worse than either substance alone. Recent evidence from animal models shows that prenatal exposure to both cannabinoids and alcohol potentiate the likelihood of alcohol-induced birth defects. The gap exists in that these evidence-based interventions in combination need to be adapted to address maternal polysubstance use during pregnancy and lactation and examine the effectiveness and cost-effectiveness. The proposed study will adapt evidence-based interventions (i.e., CM and educational components of WHC) to address maternal polysubstance use during pregnancy and lactation with contingent financial incentives on biochemically verified polysubstance abstinence during pregnancy and lactation. The text-based health promotion and referral content will also be incorporated

according to the evidence of how lifestyle, mental health, and sexual health affect maternal alcohol and substance use based on WHC educational components.

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# APPENDIX 1

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes.***

Pre-Screening Consent Form

This pre-screening consent form is used to determine whether you are eligible to take part in a study whose goal is to adapt and test an intervention to reduce polysubstance use (e.g., alcohol, tobacco, and cannabis) during pregnancy and breastfeeding. You are being invited because you are either pregnant or postpartum and have a recent history of alcohol and tobacco or cannabis use. Please carefully read this information before deciding to take part in this pre-screening. If you have any questions, please do not hesitate to ask the study staff. Your participation in this pre-screening is voluntary. If you decide not to participate, your decision will not be held against you in any way.

The purpose of this form is to obtain your consent to allow us to collect biological samples to pre-qualify your eligibility. If you agree, you will be asked to provide a urine sample for urinalysis. Your collected urine sample will be tested for alcohol, tobacco, and cannabis.

To further your participation in this study, you must test positive for alcohol and positive for cannabis or tobacco. If you test negative, you will not be eligible to participate in the study and will receive R50 compensation.

By signing this form, you are agreeing to the following:

- That you have a recent history of alcohol, tobacco, and/or cannabis use.
- You will allow staff to obtain a urine sample, which will be tested for alcohol, cannabis, and/or tobacco use.
- You understand that to further your participation in the study, you must test positive for alcohol and either tobacco or cannabis.
- You understand that your participation in pre-screening is completely voluntary, and there will be no penalty if you choose not to participate.

| **Participant's Signature** | **Date**<br>**(DD/MM/YYYY)** | **Signed at (Place)** |
|---|---|---|

# APPENDIX 2

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes***

***PLEASE DO NOT USE FULL NAMES ANYWHERE ON THIS FORM***

PARTICIPANT ID: ..... |__|__|__|__|

STAFF ID: ..... |__|__|__|__|

DATE: ..... |__|__| / |__|__| / |__|__|__|__|

DD MM YYYY

WHERE:_____

**READ:** Hello, my name is _____. I'm working on a study with pregnant and post-partum women at the South African Medical Research Council (SAMRC).

It will take less than 5 minutes to find out if you might be eligible to take part in this study. Your answers will be kept strictly confidential and you do not need to give me your name at this time. Is it OK if we ask you these questions? **(If no, thank them for their time and end the initial screener)**

## SECTION 1

1. What is your date of birth? ..... |__|__|/|__|__|/|__|__|__|__|
   DD MM YYYY

   a. And how old are you now?.....__|__|

   (If individual is under 18 then ineligible) – **PLEASE END THE SCREENER**

2. What is your place of birth? _____.

3. What is your race? (select one response)

   ***Response does NOT affect eligibility***

   Black African ..... 1
   Coloured ..... 2
   White South African ..... 3
   Asian/Indian ..... 4
   OTHER ..... 99
   [SPECIFY]_____
   REFUSED ..... -7

4. Are you currently pregnant?
   Yes……....1
   No……0 ( If no, Skip to question 5)

   a. **If yes,** w/how many week pregnant are you now (gestational age)? **Answer in weeks**:
   _____

***If participant is less than 13 weeks or greater than 28 week- PARTICIPANT IS INELIGIBLE***

***PLEASE END THE SCREENER –***

**5.** Are you currently breastfeeding with less than 3 months postpartum?

Yes……....1

No……..0

***If answered, NO to both question 4 and 5, PLEASE END THE SCREENER – PARTICIPANT IS INELIGIBLE***

6. Is your current pregnancy (or baby being breastfed) a planned pregnancy?

Planned…….....1

Unplanned…….……0

**7.** Do you drink alcohol in your current pregnancy, or while you are breastfeeding?

Yes……....1

No……..0

***If participant drinks alcohol and she is currently drinking during her pregnancy or breastfeeding, please administer an EtG test. If participant test NEGATIVE, she is <u>INELIGIBLE</u>.***

8. Do you use tobacco in your current pregnancy, or while you are breastfeeding?

Yes……....1

No……..0( If no, skip to question 9)

a. Please specify below what type of tobacco do you use (i.e. smoking, chewing)?

| |
|---|
| |

**9.** Do you use cannabis/dagga/marijuana in your current pregnancy or while you are breastfeeding?

Yes……....1

No……..0 ***(If participant, answered "NO" for BOTH question 8 and 9, PLEASE END THE SCREENER – PARTICIPANT IS INELIGIBLE)***

***_ Add interviewer prompt: As a reminder, your answer are confidential.***

***(If participant, answered "YES" for either question 8 or 9 please administer an EtG test. If tested NEGATIVE for BOTH THC and cotinine, PARTICIPANT IS INELIGIBLE)***

10. Do you plan to complete your antenatal care at this current clinic and remain to stay here for at least 3 months after delivering your baby?

Yes……....1

No……..0

***(If participant, answers "NO", PLEASE END THE SCREENER – PARTICIPANT IS INELIGIBLE)***

***11.*** Do you currently have any serious medical problems or any other reason(s) that may result in your pregnancy to be high risk?***(If participant is currently Breastfeeding, SKIP to Question 12)***

Yes……....1
No……0

***(If participant, answers "YES", PLEASE END THE SCREENER – PARTICIPANT IS INELIGIBLE)***

12. Do you currently have suicidal thoughts or attempted suicide in the past month?

Yes……....1
No……0

***(If participant, answers "YES", PLEASE PROVIDE PARTICIPANT WITH LOCATE MENTAL HEALTH RESOURCES AND END THE SCREENER – PARTICIPANT IS INELIGIBLE)***

13. Do you currently own a cell phone?

Yes……....1
No……0

***(If participant, answers "NO", PLEASE END THE SCREENER – PARTICIPANT IS INELIGIBLE)***

**14.** Have you ever been given a positive HIV test result in your lifetime?

Yes……....1
No……0

***(If participant, answers "YES", PLEASE END THE SCREENER – PARTICIPANT IS INELIGIBLE)***

**END OF SCREENER**

**SCRIPT A: If the person is NOT eligible, READ:**
Those are all of the questions I have for you. Thank you very much for your time and participation. All of the information you have provided will be kept confidential.

**SCRIPT B: If the person is eligible, READ:**
Based on your answers, you are eligible to take part in a study we are conducting to develop a behavioral intervention to improve maternal/infant health. If you have a moment now, I would like to tell you a little more about the study.

***If yes,* [READ:]**
□ If you agree to participate, I would like to schedule an appointment with you to be interviewed.

□ Before you agree to participate, we will go over this study in detail so that you will know what we will be asking of you.

Would you like to continue with the study? _____ *(If yes, continue to consent the participant).*
*IF NOT INTERESTED IN STUDY, ASK AND RECORD WHY:*

I do not have time ☐
I am worried about privacy ☐
Not a good time (patient received results/is distressed) ☐
I am not interested in being part of a study ☐
I do not have alcohol use problems ☐ Other
☐

*If other*: please tell me your reason ……..

# APPENDIX 3

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes***

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 because you are either pregnant, or postpartum with a recent history of alcohol and tobacco/cannabis use. The information in this consent form will give you the necessary details about this study to help you decide whether you would like to take part or not. 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 adapt and test an intervention to decrease polysubstance use (i.e., alcohol and tobacco/cannabis) during pregnancy and breastfeeding and to prevent adverse clinical outcomes, including Fetal Alcohol Spectrum Disorders (FASD).

**What We're Asking of You**
If you agree to participate, you will be one of 48 women (24 pregnant and 24 postpartum women) who have a recent history of using alcohol, tobacco, or cannabis during your current pregnancy or while you are breastfeeding. You will be required to complete 3 interviews as part of your participation: a screening interview, a baseline interview, and a 3-month follow-up interview. While enrolled in the study, you will be asked a series of questions during these 3 interview appointments. In addition, you will be asked to provide a blood sample and a urine sample at screening and once per month until the completion of your time in the study. You will also be asked to participate in a **Post-testing qualitative interview.** You will spend approximately one hour at each interview. Your time and inputs are very important to us since they will help us improve this program for future studies.

**Potential Risks and Discomforts.**
We don't anticipate any risks associated with taking part in this study. You might, however, feel uncomfortable providing biological samples or responding to certain interview questions. If you feel uncomfortable, please let a member of the study staff know. We want you to be aware that you will never be pressured to answer any questions or forced to provide biological samples. Participation is fully voluntary. You have the right to stop participation in the study at any time, decline to give biological samples, and/or decline to participate in an interview. We ensure you that if you decided to no longer participate in this study, your decision will not be held against you in any kind of way.

**Potential Benefits of Taking Part in the Study.**
There are no direct benefits to you for participating in this study , but the information you provide will help us gain a better understanding of how to develop an appropriate 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 must report that information to the appropriate authorities. The consent and contact forms will be stored separately to transcripts in locked file cabinets. The South African MRC ethics committee will

however have access to all data. Deidentified data will be shared with the funding body NIH and archived with NIH according to their policy.
We will use the data from the interviews to write up and publish papers in academic journals, but this data will be anonymized (we will use a participant number instead of your name). Your name will therefore not appear anywhere in any published material.

There is a small possibility that a person may gain access to the information you gave us without our permission. Every effort will be made to protect your privacy and no personal details or names will be used during the interview.

**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).

**Compensation**
While taking part in this study, you will be required to meet with study staff at the health facility once a month to provide a urine and dry blood sample that will be tested for alcohol, tobacco, cannabis and other substances. You can receive R200 for testing negative for each substance in your first month of participation in the research. Following that, your earnings will increase by R50 till the study is completed. However, if your sample tests positive for a substance, your earnings will be reduced back to R200. Additionally, you will be compensated R200 for completing screening and a baseline assessment and R300 for completing the follow-up assessment at the end of the study.

**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: petal.petersen@mrc.ac.za

Mental Health, Alcohol, Substance use and Tobacco Research Unit
Medical Research Council
P.O. Box 19070
Tygerberg
7505
Tel. 021-938 0337

**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 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 (DD/MM/YYYY) | Signed at (Place) |
|---|---|---|

## APPENDIX 4: CONTACT INFORMATION FORM

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes***

INTERVIEWERS INITIALS |__|__|

DATE: |__|__| / |__|__| / |__|__|__|__|

DD MM YYYY

PARTICIPANT ID NUMBER: |__|__|

**Instructions for Staff - Reviewing and/or Updating:** This form should be reviewed and updated at each appointment.

**READ:** As we mentioned in the consent form, we would like to collect your contact information to remind you of your next appointment. Please note that this information will be kept private. We will use the information you give us to contact you to remind you of your appointments.

Please use this form to record any additional information (e.g., nicknames, hangouts, or cell phone numbers, etc.) that will be helpful if you need to schedule an appointment for a later time or the next day. This information should help you find the participant in case they forget to meet at the scheduled location.

What is your first name, middle name and surname?

_____

What nicknames do you use?

_____

What is your cell phone number?

_____

If we can't get hold of you on this number is there anyone else we can phone who you see regularly?

| NAME AND RELATION | CELLPHONE NUMBER |
|---|---|
| 1. | 1. |
| 2. | 2. |
| 3. | 3. |

| | |
|---|---|
| 4. | 4. |

Please can you supply is with your home address?

_____
_____
_____

Please describe any relevant landmarks or any significant information we will need to locate your home address if applicable (this is particularly important if you reside in an informal settlement).

_____
_____
_____

If we cannot get hold of you by phone, can we send a project staff member to your home?

☐YES ☐ NO

Where do you usually hang out during the day?

_____

Please can you supply us with your email address if you have one?

_____

# APPENDIX 5

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes.***

*Baseline Assessment*

***PLEASE DO NOT USE FULL NAMES ANYWHERE ON THIS FORM***

PARTICIPANT ID:..... |__|__|__|__|

STAFF ID: ..... |__|__|

DATE:.....|__|__| / |__|__| / |__|__|__|__|

DD MM YYYY

WHERE:_____

**Introductions:**

**Assessor to read: We will work through the questionnaire as follows: I will ask the questions and give you the answer choices. You will be asked to pick the answer that is the closest to how you feel. I will then record your answer. The interview will take about 45 minutes to complete. There are no right or wrong answers. Please answer just what you think and feel.**

***No one at the clinic will see you answers, and you will be identified with a special participant ID.***

**A, DEMOGRAPHICS**

A1. How old are you? _____(years)

A2. What language do you speak at home?

- ☐ 1= English
- ☐ 2= Afrikaans

- ☐ 3= IsiXhosa
- ☐ 4= IsiZulu
- ☐ 5= Sesotho
- ☐ 6=SeTswana
- ☐ 7= SePedi
- ☐ 8= SiSwati
- ☐ 9= Tshi Venda
- ☐ 10= Zitsonga
- ☐ 11= IsiNdebele
- ☐ 12= Other ( Please Specfiy_____)

A3. What race are you?

- ☐ 1=Coloured
- ☐ 2= Black
- ☐ 3= Indian
- ☐ 4= White
- ☐ 5=Other ( Please specify_____)

A4. What is your current relationship status?

- ☐ 1= Has a partner
- ☐ 2= Not married and living with a partner
- ☐ 3= Married
- ☐ 4= Divorced or separated
- ☐ 5= Widow/Widower
- ☐ 6= Single
- ☐ 7 = Other (Please specify_____)

A5. What education do you have?

- ☐ 1= No Formal Education
- ☐ 2= Grade 1-7
- ☐ 3= Grade 8-12
- ☐ 4= Tertiary (College, Technicon, University)

A6. Which best describes the type of house in which you live? Please choose one answer only

1= House or brick structure on a separate stand or yard or on farm
2= Traditional dwelling/hut/structure made of traditional materials
3= Flat
4= Town/cluster/semi-detached house (simplex, duplex or triplex)
5= Unit in retirement village
6= Dwelling/house/flat/room in backyard
7= Informal dwelling/shack IN the backyard of a formal house
8= Informal dwelling/shack NOT in backyard e.g. in an informal/squatter settlement or on farm
9= Room/flatlet not in backyard but on a shared property( e.g granny flat)
10= Caravan/tent
11= Worker's hostel
12= Other (Please specify_____)

A7. Which of the following best describes your current employment status?

- ☐ 1= Unemployed and looking for work
- ☐ 2= Unemployed and not looking for work
- ☐ 3= Employed part-time
- ☐ 4= Employed full-time
- ☐ 5= Self-employed
- ☐ 6= Pensioner
- ☐ 7= Student/Scholar/Learner

A8. What is your main source of income? (Where do you get most of your money from each month?)

- ☐ 1= Formal employment
- ☐ 2= Self-employment

- ☐ 3= Odd jobs
- ☐ 4= Government grant (childhood/disability)
- ☐ 5= Income from investments
- ☐ 6= Maintenance (child support or money from ex-partner for living costs)
- ☐ 7= Scholarship/student loan
- ☐ 8= Pension
- ☐ 9= No income
- ☐ 10= Other (Please Specify _____)

A9. On average, what is your monthly income?

- ☐ 1= Less than R600
- ☐ 2= R600-R1000
- ☐ 3= R1001-R2000
- ☐ 4= R2001-R4000
- ☐ 5= More than R4000
- ☐ 6= Don't know

A10. How many people do you support with your income? _____

A11. Are you currently pregnant?

- ☐ 1= Pregnant
- ☐ 2= Postpartum (SKIP TO A13)

A12. How many weeks pregnant are you? _____ (weeks)

A13. How old is your baby?_____(months)

B4. Was your current pregnancy or baby planned?
1.Yes
0.No

A14. What is your current weight?_____(in kgs)

A15. What is your current height_____(in cms)

## B. PREGNANCY EXPERIENCES

PAST PREGNANCY EXPERIENCES

B1. How many times have you been pregnant before now? **(Excluding this pregnancy if currently pregnant or the most recent pregnancy if currently post-partum) :_____**
**(IF CURRENT PREGNANCY IS THE FIRST PREGNANCY GO TO THE QUESTION B4)**

B2. Now I would like to ask you about your past pregnancies and the health of your **last**-born child. Please note these questions **do not** refer to your current pregnancy if currently pregnant or your new-born if currently post-partum.

| | **Of these pregnancies, how many are** | | | | **Outcome of Last Pregnancy** | | | **Complications** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Nr | Still Alive | Still Birth | Abortion | Miscarriages | Full Term | Still Born | Voluntary Abortion | Yes | No | N/A |
| 1 | | | | | | | | | | |
| 2 | | | | | | | | | | |
| 3 | | | | | | | | | | |
| 4 | | | | | | | | | | |

B3. Do you have any biological children with alcohol-related disabilities from your previous pregnancies?
1.Yes

0.No

B3_a. If yes, how many? _____

**F. BREASTFEEDING HISTORY AND ATTITUDE**

If you are currently pregnant and have no other children, this section is NA.
Please skip to **Section G**

**BFH2.1** Have you ever breastfed before in your lifetime?

- ☐ 1=Yes
- ☐ 0=No

*If YES to BFA2.1*:

**BFH2A.1** How many children did you breastfeed and about how long?

| | Duration of breastfeeding |
|---|---|
| 1st child | |
| 2nd child | |
| 3rd child | |
| 4th child | |
| 5th child | |

BFH1Are you currently breastfeeding?
1= Yes
0=No

**BFH1.1** What made you decide to breastfeed?

_____
_____
_____
_____

**BFH3.1** Has your mother ever breastfed before?

- ☐ 1=Yes
- ☐ 0=No

*If YES to BFA3.1*:

**BFH3A.1** If so, how many children did she breastfeed? _____ children
**BFH3B.1** How many children did she have? _____ children

**BFH4.1** Has any of your relatives or friend ever breastfed before?

- ☐ 1=Yes
- ☐ 0=No

**C. ALCOHOL USE**

C1 Timeline follow-back

**Show participant the picture of the standard drinks.** Explain: Different alcohol containers have different amounts of alcohol. E.g a small can of beer is 1 standard drink but a quart has 2 standard drinks. The next few questions ask about the number of standard drinks you usually drink.

**Surp_p1.1** In the month before you knew you were pregnant, how many beers, how much wine, or how much liquor did you drink?* _____

**BFH5.1** In the past, have you every breastfed after consuming alcohol?
1=Yes
0=No

C2. How old were you when you had your first drink? _____ (years)

**Do you currently drink alcohol?**
**'1'=Yes**
**'0'=No**

**Alc_7dys:**From 0-7, how many days in the last 7 did you drink alcohol?____

**Past 7 day drinking ending on day 7 (yesterday)**

Please provide that number of drinks you had in a day for the last 7 days.

| **Day 1:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 2:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 3:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 4:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 5:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 6:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 7:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

**BFH6.1** Did you breastfed your child after consuming alcohol in the past week or last 7 days? Skip is answer 0 to alc_7dys_bsl

- ☐ 1=Yes
- ☐ 0=No

**BFH6.2** How many days did you use alcohol and then breastfed? _____

**CRAVING (Scale: 0-10 with 0 not at all craving for a drink to 10 extremely craving for a drink how often do you crave a drink in a week?**

| **Day 1** | **Day 2** | **Day 3** | **Day 4** | **Day 5** | **Day 6** | **Day 7(yesterday)** |
|---|---|---|---|---|---|---|
| | | | | | | |

**AUDIT-C**

C3. How often do you have a drink containing alcohol?

- ☐ 0=Never
- ☐ 1=Monthly or less
- ☐ 2=2-4 times a month
- ☐ 3=2-3 times a week
- ☐ 4=4 or more times a week

C4. How many standard drinks containing alcohol do you have on a typical day?

- ☐ 0=1 or 2
- ☐ 1=3 to 4 ( flag start)
- ☐ 2=5 to 6
- ☐ 3=7 to 9
- ☐ 4=10 or more

C5. How often do you have 4 or more drinks on one occasion?

- ☐ 0= Daily or almost daily
- ☐ 1=Weekly
- ☐ 2=Monthly
- ☐ 3=Less than monthly
- ☐ 4=Never

Would you like a referral related to your alcohol use? If, yes please provide participant with resource
1=Yes
0=No

**D. SUBSTANCE USE**

**The next few questions ask about your use of drugs other than alcohol and tobacco. We know that many people use drugs like dagga. Don't worry about telling us that you use drugs. We want to understand what is really happening, not what you think we "want to hear."** ***Here are a few questions about your use of drugs.***
***Drugs*** **include substances like dagga (ganja or weed), methamphetamine or tik, ecstasy, mandrax, cocaine, heroin, unga**

| **assist_1** In your life, which of the following substances have you ever used? (NON-MEDICAL USE ONLY) | **0= NO** | **1=YES** |
|---|---|---|
| **assist_1a**Tobacco products (cigarettes, chewing tobacco, cigars, etc.) | | |
| **assist_1b**Alcoholic beverages (beer, wine, spirits, etc.) | | |
| **assist_1c**Cannabis (marijuana, pot, grass, hash, etc.) | | |
| **assist_1d**Cocaine (coke, crack, etc.) | | |
| **assist_1e**Amphetamine-type stimulants (speed, meth, ecstasy, etc.) | | |
| **assist_1f** Inhalants (nitrous, glue, petrol, paint thinner, etc.) | | |
| **assist_1g**Sedatives or sleeping pills (diazepam, alprazolam, flunitrazepam, midazolam, etc.) | | |
| **assist_1h**Hallucinogens (LSD, acid, mushrooms, trips, ketamine, etc.) | | |
| **assist_1i** Opioids (heroin, morphine, methadone, buprenorphine, codeine, etc.) | | |
| **assist_1j**Other | | |

| **assist_2:** In the past three months, how often have you used the substances you mentioned (FIRST DRUG, SECOND DRUG, ETC)?skip if the following | 0=Never | 2=Once or Twice | 3=Monthly | 4=Weekly | 6= Daily or Almost Daily |
|---|---|---|---|---|---|
| **assist_2a**Tobacco products (cigarettes, chewing tobacco, cigars, etc.) (branching logic, if assist_1a="0) | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **assist_2b**Alcoholic beverages (beer, wine, spirits, etc.) (branching logic, if assist_1b="0') | | | | | |
| **assist_2c**Cannabis (marijuana, pot, grass, hash, etc.) (branching logic, if assist_1c="0') | | | | | |
| **assist_2d**Cocaine (coke, crack, etc.) ((branching logic, if assist_1d="0') | | | | | |
| **assist_2e**Amphetamine-type stimulants (speed, meth, ecstasy, etc.) ((branching logic, if assist_1e="0') | | | | | |
| **assist_2f** Inhalants (nitrous, glue, petrol, paint thinner, etc.) (branching logic, if assist_1f="0') | | | | | |
| **assist_2g**Sedatives or sleeping pills (diazepam, alprazolam, flunitrazepam, midazolam, etc.) ((branching logic, if assist_1g="0') | | | | | |
| **assist_2h**Hallucinogens (LSD, acid, mushrooms, trips, ketamine, etc.) ((branching logic, if assist_1h="0') | | | | | |
| **assist_2i**Opioids (heroin, morphine, methadone, buprenorphine, codeine, etc.) ((branching logic, if assist_1i="0') | | | | | |
| **assist_2j**Other(branching logic, if assist_1j="0') | | | | | |

| | | | |
|---|---|---|---|
| **assist_8:** Have you ever used any drug by injection? (NON-MEDICAL USE ONLY) | 0=No, Never | 6= Yes, in the past 3 months | 3=Yes, but not in the past 3 months |

**Surp_p2.1** Have you ever felt the need to cut down on your drug or alcohol use?

- ☐ 1= Yes
- ☐ 0= No

**MJ.Do you currently use cannabis?**
**'1'=YES**
**'0'=NO**

**MJ.1** Which of the following statements best describes your marijuana use: Would you say:

- ☐ 1 = I use marijuana regularly now – about the same amount as before finding out I was pregnant
- ☐ 2 = I use marijuana regularly now, but I've cut down since I found out I was pregnant
- ☐ 3 = I use marijuana every once in a while
- ☐ 4 = I have quit using marijuana since finding out I was pregnant
- ☐ 5 = I wasn't using marijuana around the time I found out I was pregnant, and I don't currently use marijuana

**MJ_MrngSick.1** Did you use in order to manage morning sickness during the last pregnancy?

- ☐ 1=Yes
- ☐ 0=No

**MJ_Types.1** Please specify what forms of marijuana you have used in the past: _____

**MJ_Age.1** How old were you the **first time** you used marijuana? _____

**MJ_LastUse.1** How long has it been since you **last** used marijuana? _____

**MJ_AvgUs.1 e** On how many days in a month did you use on average? _____

**MJ_7days** From 0 to 7, how many days out of the last 7 did you use cannabis? (Even if they say 0, proceed to next question.)_____

Please provide how many times a day you use cannabis in the last 7 days.

| Number of times: | 1x | 2x | 3x | 4x | 5x | 6 or more |
|---|---|---|---|---|---|---|
| Day 1 | | | | | | |
| Day 2 | | | | | | |
| Day 3 | | | | | | |
| Day 4 | | | | | | |
| Day 5 | | | | | | |
| Day 6 | | | | | | |
| Day 7 | | | | | | |

**BFMJ_7days** Did you breastfed your child after smoking cannabis in the past week or the 7 days?

- ☐ 1=Yes
- ☐ 0=No

**BFMJ_7days** How many days did you use cannabis (dagga) and then breastfed? _____

**MJ_safe.1** How safe do you think marijuana is?

- ☐ 1 = Very safe
- ☐ 2 = Somewhat safe
- ☐ 3 = Somewhat unsafe
- ☐ 4 = Very unsafe
- ☐ 5 = Don't know

**MJ_harm.1** How harmful do you believe marijuana is for your health?

- ☐ 1 = Very harmful
- ☐ 2 = Somewhat harmful
- ☐ 3 = A little harmful
- ☐ 4 = Not at all harmful
- ☐ 5 = Don't know

**E. NICOTINE DEPENDENCE**

**E1**.Do you currently smoke cigarettes?

- ☐ 1=Yes
- ☐ 0=No (IF NO, SKIP TO SECTION F.)

**Cigs_7dy** From 0-7, how many days out of the last 7 have you smoked at least puff of a tobacco product like cigarettes?

Please provide how many times a day you used cigarettes or a tobacco product in the last 7 days.

| Number of times: | 1x | 2x | 3x | 4x | 5x | 6 or more |
|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| Day 1 | | | | | | |
| Day 2 | | | | | | |
| Day 3 | | | | | | |
| Day 4 | | | | | | |
| Day 5 | | | | | | |
| Day 6 | | | | | | |
| Day 7 | | | | | | |

E2.Did you breastfed your child after using cigarettes or tobacco products in the past week or the last 7 days?

- ☐ 1=Yes
- ☐ 0=No

E3.How many days after using cigarettes or tobacco did you breastfed? _____

E4. Have you used other substances other than tobacco and/or cannabis ( i.e Cocaine, Amphetamine, Opioids etc.) in the past week and then breastfed?

- ☐ 1=Yes
- ☐ 0=No

E4.aPlease specify what substance(s) you use in the last 7 days?_____

E4.b How many days did you use other substances and then breastfed? _____

Do you think you will need any of the following services? Only refer to things you will need yourself.

| | | YES ▼ | NO ▼ | DK/Unsure ▼ | REF ▼ | |
|---|---|---|---|---|---|---|
| a. | Employment or job placement services | 1 | 2 | -4 | -7 | |
| b. | Schooling services | 1 | 2 | -4 | -7 | |
| c. | Housing services | 1 | 2 | -4 | -7 | |
| d. | Financial assistance services | 1 | 2 | -4 | -7 | |
| e. | Food assistance services | 1 | 2 | -4 | -7 | |
| f. | Legal services (e.g., lay a charge) | 1 | 2 | -4 | -7 | |
| g. | Transportation services | 1 | 2 | -4 | -7 | |
| h. | Getting medical/healthcare | 1 | 2 | -4 | -7 | |
| i. | Self-help groups (for example Alcoholics Anonymous or Alanon) | 1 | 2 | -4 | -7 | |
| j. | Physical and/or sexual abuse counseling services | 1 | 2 | -4 | -7 | |
| k. | Mental health services (e.g. for depression, stress) | 1 | 2 | -4 | -7 | |
| l. | Child care services | 1 | 2 | -4 | -7 | |
| m. | Counseling (individual, family, couples) | 1 | 2 | -4 | -7 | |
| n. | Substance abuse rehab/treatment | 1 | 2 | -4 | -7 | |

**H. PSYCHOLOGICAL DISTRESS/DEPRESSION**

**GENERALALISED ANXIETY DISORDER-7 (GAD-2)**

Over the last 2 weeks, how often have you been bothered by the following problems?

| | Not at all (0) | Several days (1) | More than half the days (2) | Nearly every day (3) |
|---|---|---|---|---|
| **gad2.1** Feeling nervous, anxious, or on the edge | | | | |
| **gad2.2**Not being able to stop or control worrying | | | | |

**EVERYDAY DISCRIMINATION SCALE(EDS)**

In your day-to-day, life how often do any of the following things happen to you?

| | Never | Less than once a year | A few times a year | A few times a month | At least once a week | Almost every day |
|---|---|---|---|---|---|---|
| **eds1.1**. You are treated with less courtesy than other people are. | | | | | | |
| **eds2.1**. You are treated with less respect than other people are. | | | | | | |
| **eds3.1**. You receive poorer service than others. | | | | | | |
| **eds4.1**. A doctor or nurse acts as if he or she thinks you are not smart. | | | | | | |
| **eds5.1**. A doctor or nurse ats as if he or she is afraid of you. | | | | | | |
| **eds6.1** A doctor or nurse ats as if he or she is better than you. | | | | | | |
| **eds7.1**. You feel like a doctor or nurse is not listening to what you were saying | | | | | | |

**INTERVIEWER: Asked only of those answering " A few times a year" or more frequently to at least one question**
**Eds10.1** What do you think is the main reason for these experiences (Check all that applies)

- ☐ 1= Your Ancestry or National Origins
- ☐ 2.= Your Gender
- ☐ 3= Your Race
- ☐ 4= Your Age
- ☐ 5= Your Religion
- ☐ 6= Your Height
- ☐ 7= Your Weight
- ☐ 8= Some other Aspect of Your Physical Appearance
- ☐ 9= Your Sexual Orientation
- ☐ 10= Your Education or Income Level

- ☐ 11= A physical disability
- ☐ 12= Your shade of skin color (NSAL)
- ☐ 13= Your tribe (SASH)
- ☐ 14=Pregnant
- ☐ 15= Substance Use
- ☐ 16= Cannabis Use
- ☐ 17= Tobacco Use
- ☐ 18= Other (SPECIFY) _____

**EDINBURGH POSTNATAL DEPRESSION SCALE (EPDS)**

As you are pregnant or have recently had a baby, we would like to know how you are feeling? Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

**In the past 7 days….**

**Edps1.** I have been able to see the funny side of things:
- ☐ 0= As much as I always could
- ☐ 1= Not quite so much now
- ☐ 2= Definitely not so much now
- ☐ 3= Not at all

**Edps2.** I have looked forward with enjoyment to things.
- ☐ 0= As much as I ever did
- ☐ 1= Rather less that I used to
- ☐ 2= Definitely less than I used to
- ☐ 3= Hardly at all

**Edps3.**I have blamed myself unnecessarily when things went wrong
- ☐ 3= Yes, most of the time
- ☐ 2= Yes, some of the time
- ☐ 1= Not very often
- ☐ 0= No, never

**Edps4.** I have been anxious or worried for no good reason
- ☐ 0= No, not at all
- ☐ 1= Hardly ever
- ☐ 2= Yes, sometimes
- ☐ 3= Yes, very often

**Edps5.** I have felt scared or panicky for no very good reason
- ☐ 3= Yes, quite a lot
- ☐ 2= Yes, sometimes
- ☐ 1= No, not much
- ☐ 0= No, not at all

**Edps6.** Things have been getting to me.
- ☐ 3= Yes, most of the time I have not been able to cope at all
- ☐ 2= Yes, sometimes I haven't been able to cope as well as usual
- ☐ 1= No, most of the time I have copes quite well
- ☐ 0= No, I have been coping as well as ever

**Edps.7** I have been so unhappy that I have had difficulty sleeping.
- ☐ 3= Yes, most of the time
- ☐ 2= Yes, some of the time
- ☐ 1= Not very often
- ☐ 0= No, never

**Edps8.** I have felt sad or miserable.
- ☐ 3= Yes, most of time
- ☐ 2= Yes, quite often

- ☐ 1= Not very often
- ☐ 0= No, not at all

**Edps9.** I have been so unhappy that I have been crying

- ☐ 3= Yes, most of the time
- ☐ 2= Yes, quite often
- ☐ 1= Only occasionally
- ☐ 0= No, never

**Edps10.** The thought of harming myself has occurred

- ☐ 3= Yes, quite often
- ☐ 2= Sometimes
- ☐ 1= Hardly ever

## I. VIOLENCE AND SEXUAL RISK EXPOSURE

***NO matter how hard people try, they sometimes have conflicts or disagreements. People can try various ways to settle their differences. I'm going to read a list of some things that you may have done when you had a disagreement.***

I1. In the past 90 days, have you had a disagreement in which you…?

**NOTE: READ LIST AND MARK A RESPONSE FOR EACH ITEM**

| | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|
| a. Insulted or swore at someone | 1 | 2 | -4 | -7 |
| b. Threatened to hit or throw something at another person | 1 | 2 | -4 | -7 |
| c. Threw something at someone | 1 | 2 | -4 | -7 |
| d. Pushed, grabbed, or shoved someone | 1 | 2 | -4 | -7 |
| e. Slapped another person | 1 | 2 | -4 | -7 |
| f. Kicked, bit, or hit someone | 1 | 2 | -4 | -7 |
| g. Hit or tried to hit anyone with something (an object) | 1 | 2 | -4 | -7 |
| h. Beat up someone | 1 | 2 | -4 | -7 |
| i. Threatened anyone with a knife or gun | 1 | 2 | -4 | -7 |
| j. Used a knife or gun on another person | 1 | 2 | -4 | -7 |

**LOGIC: IF NO MAIN SEXUAL PARTNER (L9=NO, DK/UNSURE, OR REFUSED) SKIP TO I3**

***Now I would like to ask you about things that your main sexual partner may have done to you. Let me***

***remind you that this information will remain strictly confidential.***

I2. In the past 90 days, has your **main sexual partner**…?

**NOTE: READ LIST AND MARK A RESPONSE FOR EACH ITEM**

| | | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|---|
| a. | Abused you emotionally, that is, did or said things to make you feel very bad about yourself or your life | 1 | 2 | -4 | -7 |
| b. | Attacked you with a gun, knife, stick, bottle, or other weapon | 1 | 2 | -4 | -7 |
| c. | Hurt you by striking or beating you to the point that you had bruises, cuts, or broken bones, or otherwise physically abused you | 1 | 2 | -4 | -7 |
| d. | Pressured or forced you to participate in sexual acts against your will | 1 | 2 | -4 | -7 |

I3. Has anyone ever physically hurt you (i.e., someone hurt you by striking or beating you to the point that you had bruises, cuts, or broken bones)?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED, SKIP TO I8.**

I4. **(HAND RESPONDENT SHOWCARD O-1)** When was the last time you were physically hurt?

Within the past two days ..... 1
3-7 days ago ..... 2
1-4 weeks ago ..... 3
1-3 months ago ..... 4
4-12 months ago ..... 5
More than 12 months ago ..... 6

DK/UNSURE ..... -4
REFUSED ..... -7

I4a. The last time you were physically hurt did you seek medical help?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4

REFUSED..... -7

I4b. (**HAND RESPONDENT SHOWCARD O-2)** The last time you were physically hurt, who hurt you?

Main sexual partner..... 1
Client..... 2
Male relative ..... 3
Female relative..... 4
Friend/acquaintance/peer ..... 5
Stranger (not a client)..... 6
Big mama or pimp ..... 7
Police ..... 8
Drug dealer..... 9
Security guard ..... 10
OTHER ..... 99

**Specify:** _____

DK/UNSURE..... -4
REFUSED..... -7

I5. How old were you when you were first physically hurt? (( *ENTER "NEG4" if DK/UNSURE or "NEG7" if REFUSED)*

AGE .....|__|__|

DK/UNSURE.....-4
REFUSED.....-7

I5a. (**HAND RESPONDENT SHOWCARD O-2)** The first time you were physically hurt, who hurt you?

Main sexual partner..... 1
Client..... 2
Male relative ..... 3
Female relative..... 4
Friend/acquaintance/peer ..... 5
Stranger (not a client)..... 6
Big mama or pimp ..... 7
Police ..... 8
Drug dealer..... 9
Security guard ..... 10
OTHER ..... 99

**Specify:** _____

DK/UNSURE..... -4
REFUSED..... -7

I6. Have you ever gone to file a complaint to the police after you have been physically hurt?

YES..... 1
NO..... 2

DK/UNSURE..... -4
REFUSED..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I8**

I7a. Was there a court case following your complaint to the police?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

I7b. Was there a conviction?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

I8. Has anyone ever pressured you or forced you to participate in sexual acts against your will?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED, SKIP TO I14**

I9. (**HAND RESPONDENT SHOWCARD O-1)** When was the last time you were pressured or forced to participate in sexual acts against your will?

Within the past two days ..... 1
3-7 days ago ..... 2
1-4 weeks ago ..... 3
1-3 months ago ..... 4
4-12 months ago ..... 5
More than 12 months ago ..... 6

DK/UNSURE ..... -4
REFUSED ..... -7

I9a. (**HAND RESPONDENT SHOWCARD O-2)** The last time you were pressured or forced to have sex, who

pressed or forced you?

Main sexual partner..... 1
Client..... 2
Male relative ..... 3
Female relative..... 4
Friend/acquaintance/peer ..... 5
Stranger (not a client)..... 6
Big mama or pimp ..... 7
Police ..... 8
Drug dealer..... 9
Security guard ..... 10
OTHER ..... 99

**Specify:** _____

DK/UNSURE..... -4
REFUSED..... -7

I10. How old were you when you were <u>first</u> pressed or forced to have sex?

AGE .....|__|__|

DK/UNSURE.....-4
REFUSED.....-7

I10a. (**HAND RESPONDENT SHOWCARD O-2)** The <u>first time</u> you were pressured or forced to have sex, who pressured or forced you?

Main sexual partner ..... 1
Client ..... 2
Male relative ..... 3
Female relative ..... 4
Friend/acquaintance/peer ..... 5
Stranger (not a client) ..... 6
Big mama or pimp ..... 7
Police ..... 8
Drug dealer ..... 9
Security guard ..... 10
OTHER ..... 99

**Specify:** _____

DK/UNSURE ..... -4
REFUSED ..... -7

I11. Have you ever gone to file a complaint to the police after you have been pressured or forced to have sex?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I13a.**

I12a. Has there ever been a court case following your complaint to the police?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I13a.**

I12b. Has there ever been a conviction?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

I13a. The last time you were pressured or forced to have sex did you seek medical help?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

I13b. The last time you were pressured or forced to have sex did you seek rape counseling?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

I14. Are you currently concerned that in the near future (or next 30 days) that someone might…?

**NOTE: READ LIST AND MARK A RESPONSE FOR EACH ITEM**

| | | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|---|
| a. | Attack you with a weapon | 1 | 2 | -4 | -7 |
| b. | Abuse you physically | 1 | 2 | -4 | -7 |
| c. | Make you engage in sexual acts against your will | 1 | 2 | -4 | -7 |
| d. | Abuse you emotionally | 1 | 2 | -4 | -7 |

***Now I want to ask you what you think about men's and women's roles.***

I15. **(HAND RESPONDENT SHOWCARD O-4)** Now I am going to ask you to respond to some statements about whether or not it is acceptable for a man to hit or beat a woman in a variety of circumstances. Please tell me how much you AGREE or DISAGREE with the following statements:

| | | Strongly Agree ▼ | Agree ▼ | Neither agree or disagree ▼ | Disagree ▼ | Strongly Disagree ▼ | DK ▼ | REF ▼ |
|---|---|---|---|---|---|---|---|---|
| a. | She does not complete her household work to his satisfaction. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| b. | She disobeys him | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| c. | She refuses to have sexual relations with him. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| d. | She asks him whether he has other girlfriends. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| e. | He suspects that she has been unfaithful. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| f. | He learns that she has been unfaithful. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| g. | She asks him to use a condom. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |

**LOGIC: IF NO MAIN SEXUAL PARTNER (L9 = NO, DK/UNSURE, OR REFUSED) SKIP TO SECTION J**

I16. If you were having trouble with your main sexual partner, are any of the following "safe places" where you can escape…?

| | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|
| a. Your main sexual partner's family home. | 1 | 2 | -4 | -7 |
| b. Your family home. | 1 | 2 | -4 | -7 |
| c. House of friend/neighbor. | 1 | 2 | -4 | -7 |
| d. Police. | 1 | 2 | -4 | -7 |
| e. Church/mosque (Place of worship). | 1 | 2 | -4 | -7 |
| f. Hospital. | 1 | 2 | -4 | -7 |
| g. Women's shelter. | 1 | 2 | -4 | -7 |
| h. Other, specify: _____ | 1 | 2 | -4 | -7 |

***Now I am going to ask you about things that may have happened between you and your main sexual partner in the past month.***

I17. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often have you and your main sexual partner argued or gotten in a verbal fight?

Daily or almost daily ..... 1
2 to 3 times a week ..... 2
1 time a week ..... 3
2 to 3 times a month ..... 4
1 time a month ..... 5
Less than 1 time a month ..... 6
Never ..... 7

DK/UNSURE ..... -4
REFUSED ..... -7

I18. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often has your drug or alcohol use caused problems between you and your main sexual partner?

Daily or almost daily ..... 1
2 to 3 times a week ..... 2
1 time a week ..... 3
2 to 3 times a month ..... 4
1 time a month ..... 5
Less than 1 time a month ..... 6
Never ..... 7

DK/UNSURE ..... -4
REFUSED ..... -7

I19. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often did your main sexual partner use alcohol to the point of intoxication?

Daily or almost daily ..... 1
2 to 3 times a week ..... 2
1 time a week ..... 3
2 to 3 times a month ..... 4
1 time a month ..... 5
Less than 1 time a month ..... 6
Never ..... 7

DK/UNSURE ..... -4
REFUSED ..... -7

I20. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often did your main sexual partner use drugs, including dagga or marijuana?

Daily or almost daily ..... 1
2 to 3 times a week ..... 2
1 time a week ..... 3
2 to 3 times a month ..... 4
1 time a month ..... 5
Less than 1 time a month ..... 6
Never ..... 7

DK/UNSURE ..... -4
REFUSED ..... -7

I21. At any time in the last 30 days, did your main sexual partner push you, grab you, shove you, or hit you?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I123**

I22. **(HAND RESPONDENT SHOWCARD O-6)** In the past 30 days when your main sexual partner did any of these things, how often did this happen after he/she had drunk alcohol or used drugs?

Always ..... 1
More than half the time ..... 2
Half the time ..... 3
Less than half the time ..... 4
Never ..... 5

DK/UNSURE ..... -4
REFUSED ..... -7

I23. In the last 30 days, did you push, grab, shove, or hit your main sexual partner?

YES ..... 1
NO ..... 2

DK/UNSURE ..... -4
REFUSED ..... -7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO SRP**

I24. **(HAND RESPONDENT SHOWCARD O-6)** In the past 30 days when you pushed, grabbed, shoved, or hit your main sexual partner, how often did this happen after you had drunk alcohol or used drugs?

Always ..... 1
More than half the time ..... 2
Half the time ..... 3
Less than half the time ..... 4
Never ..... 5

DK/UNSURE ..... -4

**Sexual Relationship Power Scale (SRP)**

**INTERVIEWER READ OUT LOUD:** Now I am going to read a list of things that might describe your current partner. Please tell me how closely this describes your current partner.

| During the past week…… | Strongly Agree | Agree | Disagree | Strongly Disagree |
|---|---|---|---|---|
| **srp1.1** If I asked my partner to use a condom, he would get violent | | | | |
| **srp2.1** If I asked my partner to use a condom, he would get angry | | | | |
| **srp3.1** Most of the time, we do what my partner wants to do | | | | |
| **srp4.1** My partner won't let me wear certain things | | | | |
| **srp5.1**When my partner and I are together, I'm pretty quiet | | | | |
| **srp6.1** My partner has more say than I do about important decisions that affect us. | | | | |
| **srp7.1** My partner tells me who I can spend time with | | | | |
| **srp8.1** If I asked my partner to use a condom, he would think I'm having sex with other people. | | | | |
| **srp9.1** I feel trapped or stuck in our relationship | | | | |
| **srp10.1** My partner does what he wants, even if I do not want him to. | | | | |
| **srp11.1** I am more committed to our relationship than my partner is | | | | |
| **srp12.1** My partner gets more out of our relationship than I do. | | | | |
| **srp13.1** My partner always wants to know where I am. | | | | |
| **srp14.1** My partner always wants to know where I am | | | | |
| **srp15.1**My partner might be having sex with someone else. | | | | |

**INTERVIEWER READ OUT LOUD:** Now I am going to read a list of things that might describe your current partner. Please tell me how closely this describes your current partner.

| **During the past week……** | Your Partner | BOTH of you Equally | You |
|---|---|---|---|
| **srp16.1** Who usually has more say about whose friends to go out with? | | | |
| **srp17.1** Who usually has more say about whether you have sex? | | | |
| **srp18.1** Who usually has more say about what you do together? | | | |
| **srp19.1** Who usually has more say about how often you seen each other? | | | |
| **srp20.1** Who usually has more say about when you talk about serious things? | | | |
| **srp21.1** In general, who do you think has more power in your relationship? | | | |
| **srp22.1** Who usually has more say about whether you use condoms? | | | |

| | | | |
|---|---|---|---|
| **srp23.1** Who usually has more say about what type of sexual acts you do? | | | |

## K. PERSONAL SELF-CONCEPT (PSC) QUESTIONNAIRE

| *Item num.* | *Statement* | Totally Disagree | Disagree | Neither Agree nor Disagree | Agree | Totally Agree |
|---|---|---|---|---|---|---|
| 1 | (SF) I am satisfied with what I am achieving in my life. | 1 | 2 | 3 | 4 | 5 |
| 2 | (AU)[a] I depend on other people more than the majority of those I know. | 1 | 2 | 3 | 4 | 5 |
| 3 | (ESC) If I'm feeling down, I find it hard to snap out of it. | 1 | 2 | 3 | 4 | 5 |
| 4 | (SF) So far, I have achieved every important goal I have set myself. | 1 | 2 | 3 | 4 | 5 |
| 5 | (HON) I am a trustworthy person. | 1 | 2 | 3 | 4 | 5 |
| 6 | (AU) In order to do anything, I first need other people's approval. | 1 | 2 | 3 | 4 | 5 |
| 7 | (ESC) I consider myself to be a very uptight and highly strung person. | 1 | 2 | 3 | 4 | 5 |
| 8 | (SF) I have yet to achieve anything I consider to be important in my life. | 1 | 2 | 3 | 4 | 5 |
| 9 | (HON) I am a man/woman of my word. | 1 | 2 | 3 | 4 | 5 |
| 10 | (AU) I find it hard to embark on anything without other people's support. | 1 | 2 | 3 | 4 | 5 |
| 11 | (ESC) I am more sensitive than the majority of people. | 1 | 2 | 3 | 4 | 5 |
| 12 | (SF) I have always overcome any difficulties I have encountered in my life. | 1 | 2 | 3 | 4 | 5 |
| 13 | (HON)[a] I am a decent, honest person. | 1 | 2 | 3 | 4 | 5 |
| 14 | (AU) When taking a decision, I depend too much on other people's opinions. | 1 | 2 | 3 | 4 | 5 |
| 15 | (SF) If I could start my life over again, I would not change very much. | 1 | 2 | 3 | 4 | 5 |
| 16 | (HON)[a] I try not to do anything that might hurt others. | 1 | 2 | 3 | 4 | 5 |
| 17 | (AU) I find it difficult to take decisions on my own. | 1 | 2 | 3 | 4 | 5 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 18 | (ESC) I am an emotionally strong person. | 1 | 2 | 3 | 4 | 5 |
| 19 | (SF) I feel proud of how I am managing my life. | 1 | 2 | 3 | 4 | 5 |
| 20 | (ESC) I suffer too much when something goes wrong. | 1 | 2 | 3 | 4 | 5 |
| 21 | (HON) My promises are sacred. | 1 | 2 | 3 | 4 | 5 |
| 22 | (ESC)[a] I know how to look after myself so as not to suffer. | 1 | 2 | 3 | 4 | 5 |

*Note.* SF: Self-fulfillment; AU: Autonomy; ESC: Emotional adjustment; HON: Honesty. [a]Items eliminated from the definitive version of the questionnaire.

# APPENDIX 6

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes.***

FU assesssment

***PLEASE DO NOT USE FULL NAMES ANYWHERE ON THIS FORM***

PARTICIPANT ID:..... |__|__|__|__|

STAFF ID: ..... |__|__|

DATE:.....|__|__| / |__|__| / |__|__|__|__|

DD MM YYYY

WHERE:_____

**Introduction**

**Assessor to read: We will work through the questionnaire as follows: I will ask the questions and give you the answer choices. You will be asked to pick the answer that is the closest to how you feel. I will then record your answer. The interview will take about 45 minutes to complete. There are no right or wrong answers. Please answer just what you think and feel.**

***No one at the clinic will see you answers, and you will be identified with a special participant ID.***

**Are you currently pregnant?**
**1= YES**
**0=NO**

**Are you currently breastfeeding?**
**1=YES**
**0=NO**

**ALCOHOL USE**

C1 Timeline follow-back
Show participant the picture of the standard drinks. Explain: Different alcohol containers have different amounts of alcohol. E.g a small can of beer is 1 standard drink but a quart has 2 standard drinks. The next few questions ask about the number of standard drinks you usually drink.


**Are you currently drinking alcohol?**

**1=YES**
**0=No**

**Alc_7dys:** From 0-7, how many days in the last 7 did you drink alcohol? _____

Please provide that number of drinks you had in a day for the last 7 days.

| **Day 1:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 2:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 3:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 4:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 5:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 6:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

| **Day 7:** | |
|---|---|
| **Date:** | DD/MM/YYYY |
| | # drinks/ containers |
| Beer | |
| Liquor | |
| Wine | |
| Cider | |

**BFH6.1** Did you breastfed your child after consuming alcohol in the past week or last 7 days?

- ☐ 1=Yes
- ☐ 0=No

**BFH6.2** How many days did you use alcohol and then breastfed? _____

**CRAVING** (Scale: 0-10 with 0 not at all craving for a drink to 10 extremely craving for a drink)

| Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7(yesterday) |
|---|---|---|---|---|---|---|
| | | | | | | |

**AUDIT-C**

C3. How often do you have a drink containing alcohol?

- ☐ 0=Never
- ☐ 1=Monthly or less
- ☐ 2=2-4 times a month
- ☐ 3=2-3 times a week
- ☐ 4=4 or more times a week

C4. How many standard drinks containing alcohol do you have on a typical day?

- ☐ 0=1 or 2
- ☐ 1=3 to 4
- ☐ 2=5 to 6
- ☐ 3=7 to 9
- ☐ 4=10 or more

C5. How often do you have four or more drinks on one occasion?

- ☐ 0= Daily or almost daily
- ☐ 1=Weekly
- ☐ 2=Monthly
- ☐ 3=Less than monthly
- ☐ 4=Never

**DRUG USE ( are these questions still needed if asked at bsl)**

| **assist_1** In your life, which of the following substances have you ever used? (NON-MEDICAL USE ONLY) | **0= NO** | **1=YES** |
|---|---|---|
| **assist_1a**Tobacco products (cigarettes, chewing tobacco, cigars, etc.) | | |
| **assist_1b**Alcoholic beverages (beer, wine, spirits, etc.) | | |
| **assist_1c**Cannabis (marijuana, pot, grass, hash, etc.) | | |
| **assist_1d**Cocaine (coke, crack, etc.) | | |
| **assist_1e**Amphetamine-type stimulants (speed, meth, ecstasy, etc.) | | |
| **assist_1f** Inhalants (nitrous, glue, petrol, paint thinner, etc.) | | |
| **assist_1g**Sedatives or sleeping pills (diazepam, alprazolam, flunitrazepam, midazolam, etc.) | | |
| **assist_1h**Hallucinogens (LSD, acid, mushrooms, trips, ketamine, etc.) | | |
| **assist_1i** Opioids (heroin, morphine, methadone, buprenorphine, codeine, etc.) | | |
| **assist_1j**Other | | |

| **assist_2:** In the past three months, how often have you used the substances you mentioned (FIRST DRUG, SECOND DRUG, ETC)? | 0=Never | 2=Once or Twice | 3=Monthly | 4=Weekly | 6= Daily or Almost Daily |
|---|---|---|---|---|---|
| **assist_2a**Tobacco products (cigarettes, chewing tobacco, cigars, etc.) | | | | | |
| **assist_2b**Alcoholic beverages (beer, wine, spirits, etc.) | | | | | |
| **assist_2c**Cannabis (marijuana, pot, grass, hash, etc.) | | | | | |
| **assist_2d**Cocaine (coke, crack, etc.) | | | | | |
| **assist_2e**Amphetamine-type stimulants (speed, meth, ecstasy, etc.) | | | | | |
| **assist_2f** Inhalants (nitrous, glue, petrol, paint thinner, etc.) | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **assist_2g**Sedatives or sleeping pills (diazepam, alprazolam, flunitrazepam, midazolam, etc.) | | | | | |
| **assist_2h**Hallucinogens (LSD, acid, mushrooms, trips, ketamine, etc.) | | | | | |
| **assist_2i**Opioids (heroin, morphine, methadone, buprenorphine, codeine, etc.) | | | | | |
| **assist_2j**Other | | | | | |

| | | | |
|---|---|---|---|
| **assist_8:** Have you ever used any drug by injection? (NON-MEDICAL USE ONLY) | 0=No, Never | 6= Yes, in the past 3 months | 3=Yes, but not in the past 3 months |

**MJ.Do you currently use cannabis?**
**'1'=YES**
**'0'=NO**

**MJ_7days** From 0 to 7, how many days out of the last 7 did you smoke cannabis? (Even if they say 0, proceed to next question.)_____

If yes, Please provide how many times a day you use cannabis in the last 7 days.

| Number of times: | 1x | 2x | 3x | 4x | 5x | 6 or more |
|---|---|---|---|---|---|---|
| Day 1 | | | | | | |
| Day 2 | | | | | | |
| Day 3 | | | | | | |
| Day 4 | | | | | | |
| Day 5 | | | | | | |
| Day 6 | | | | | | |
| Day 7 | | | | | | |

**BFMJ_7days** Did you breastfed your child after smoking cannabis in the past week or the 7 days?

- ☐ 1=Yes
- ☐ 0=No

**BFMJ_7days** How many days did you use cannabis and then breastfed? _____

**NICOTINE DEPENDENCE**

**Are you currently smoking tobacco?**
**1=Yes**
**0=No**

**Cigs_7dy** From 0-7, how many days out of the last 7 have you smoked at least puff of a tobacco product like cigarettes?

Please provide how many times a day you used cigarettes or a tobacco product in the last 7 days.

| Number of times: | 1x | 2x | 3x | 4x | 5x | 6 or more |
|---|---|---|---|---|---|---|
| Day 1 | | | | | | |
| Day 2 | | | | | | |
| Day 3 | | | | | | |
| Day 4 | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Day 5 | | | | | | |
| Day 6 | | | | | | |
| Day 7 | | | | | | |

Did you breastfed your child after using cigarettes or tobacco products in the past week or the last 7 days?

- ☐ 1=Yes
- ☐ 0=No

How many days after using cigarettes or tobacco did you breastfed? _____

Have you used other substances other than tobacco and/or cannabis ( i.e Cocaine, Amphetamine, Opioids etc.) in the past week and then breastfed?

- ☐ 1=Yes
- ☐ 0=No

How many days did you use other substance(s) and then breastfed? _____

Please specify what substance(s) you use:_____

Do you think you will need any of the following services? Only refer to things you will need yourself.

| | | YES ▼ | NO ▼ | DK/Unsure ▼ | REF ▼ |
|---|---|---|---|---|---|
| a. | Employment or job placement services | 1 | 2 | -4 | -7 |
| b. | Schooling services | 1 | 2 | -4 | -7 |
| c. | Housing services | 1 | 2 | -4 | -7 |
| d. | Financial assistance services | 1 | 2 | -4 | -7 |
| e. | Food assistance services | 1 | 2 | -4 | -7 |
| f. | Legal services (e.g., lay a charge) | 1 | 2 | -4 | -7 |
| g. | Transportation services | 1 | 2 | -4 | -7 |
| h. | Getting medical/healthcare | 1 | 2 | -4 | -7 |
| i. | Self-help groups (for example Alcoholics Anonymous or Alanon) | 1 | 2 | -4 | -7 |
| j. | Physical and/or sexual abuse counseling services | 1 | 2 | -4 | -7 |
| k. | Mental health services (e.g. for depression, stress) | 1 | 2 | -4 | -7 |
| l. | Child care services | 1 | 2 | -4 | -7 |
| m. | Counseling (individual, family, couples) | 1 | 2 | -4 | -7 |
| n. | Substance abuse rehab/treatment | 1 | 2 | -4 | -7 |

Would you like a referral related to your alcohol use? If, yes please provide participants with resource.
1=Yes
0=No

## H. PSYCHOLOGICAL DISTRESS/DEPRESSION

### GENERALALISED ANXIETY DISORDER-7 (GAD-2)

Over the last 2 weeks, how often have you been bothered by the following problems?

| | Not at all (0) | Several days (1) | More than half the days (2) | Nearly every day (3) |
|---|---|---|---|---|
| **gad2.1** Feeling nervous, anxious, or on the edge | | | | |
| **gad2.2**Not being able to stop or control worrying | | | | |

### EVERYDAY DISCRIMINATION SCALE(EDS)

In your day-to-day, life how often do any of the following things happen to you?

| | Never | Less than once a year | A few times a year | A few times a month | At least once a week | Almost every day |
|---|---|---|---|---|---|---|
| **eds1.1**. You are treated with less courtesy than other people are. | | | | | | |
| **eds2.1**. You are treated with less respect than other people are. | | | | | | |
| **eds3.1**. You receive poorer service than others. | | | | | | |
| **eds4.1**. A doctor or nurse acts as if he or she thinks you are not smart. | | | | | | |
| **eds5.1**. A doctor or nurse ats as if he or she is afraid of you. | | | | | | |
| **eds6.1** A doctor or nurse ats as if he or she is better than you. | | | | | | |
| **eds7.1**. You feel like a doctor or nurse is not listening to what you were saying | | | | | | |

**INTERVIEWER: Asked only of those answering " A few times a year" or more frequently to at least one question**
**Eds10.1** What do you think is the main reason for these experiences (Check all that applies)

- ☐ 1= Your Ancestry or National Origins
- ☐ 2.= Your Gender
- ☐ 3= Your Race
- ☐ 4= Your Age
- ☐ 5= Your Religion
- ☐ 6= Your Height
- ☐ 7= Your Weight
- ☐ 8= Some other Aspect of Your Physical Appearance
- ☐ 9= Your Sexual Orientation
- ☐ 10= Your Education or Income Level
- ☐ 11= A physical disability
- ☐ 12= Your shade of skin color (NSAL)
- ☐ 13= Your tribe (SASH)
- ☐ 14=Pregnant
- ☐ 15= Substance Use
- ☐ 16= Cannabis Use

- ☐ 17= Tobacco Use
- ☐ 18= Other (SPECIFY) _____

**EDINBURGH POSTNATAL DEPRESSION SCALE (EPDS)**

As you are pregnant or have recently had a baby, we would like to know how you are feeling? Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

**In the past 7 days….**

**Edps1.** I have been able to see the funny side of things:
- ☐ 0= As much as I always could
- ☐ 1= Not quite so much now
- ☐ 2= Definitely not so much now
- ☐ 3= Not at all

**Edps2.** I have looked forward with enjoyment to things.
- ☐ 0= As much as I ever did
- ☐ 1= Rather less that I used to
- ☐ 2= Definitely less than I used to
- ☐ 3= Hardly at all

**Edps3.**I have blamed myself unnecessarily when things went wrong
- ☐ 3= Yes, most of the time
- ☐ 2= Yes, some of the time
- ☐ 1= Not very often
- ☐ 0= No, never

**Edps4.** I have been anxious or worried for no good reason
- ☐ 0= No, not at all
- ☐ 1= Hardly ever
- ☐ 2= Yes, sometimes
- ☐ 3= Yes, very often

**Edps5.** I have felt scared or panicky for no very good reason
- ☐ 3= Yes, quite a lot
- ☐ 2= Yes, sometimes
- ☐ 1= No, not much
- ☐ 0= No, not at all

**Edps6.** Things have been getting to me.
- ☐ 3= Yes, most of the time I have not been able to cope at all
- ☐ 2= Yes, sometimes I haven't been able to cope as well as usual
- ☐ 1= No, most of the time I have copes quite well
- ☐ 0= No, I have been coping as well as ever

**Edps.7** I have been so unhappy that I have had difficulty sleeping.
- ☐ 3= Yes, most of the time
- ☐ 2= Yes, some of the time
- ☐ 1= Not very often
- ☐ 0= No, never

**Edps8.** I have felt sad or miserable.
- ☐ .3= Yes, most of time

- ☐ 2= Yes, quite often
- ☐ 1= Not very often
- ☐ 0= No, not at all

**Edps9.** I have been so unhappy that I have been crying
- ☐ 3= Yes, most of the time
- ☐ 2= Yes, quite often
- ☐ 1= Only occasionally
- ☐ 0= No, never

**Edps10.** The thought of harming myself has occurred
- ☐ 3= Yes, quite often
- ☐ 2= Sometimes
- ☐ 1= Hardly ever
- ☐ 0= Never

## VIOLENCE AND SEXUAL RISK EXPOSURE

**Do you currently have a main partner?**
**1=YES**
**0=NO**

***NO matter how hard people try, they sometimes have conflicts or disagreements. People can try various ways to settle their differences. I'm going to read a list of some things that you may have done when you had a disagreement.***

I1. In the past 90 days, have you had a disagreement in which you…?

**NOTE: READ LIST AND MARK A RESPONSE FOR EACH ITEM**

| | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|
| k. Insulted or swore at someone | 1 | 2 | -4 | -7 |
| l. Threatened to hit or throw something at another person | 1 | 2 | -4 | -7 |
| m. Threw something at someone | 1 | 2 | -4 | -7 |
| n. Pushed, grabbed, or shoved someone | 1 | 2 | -4 | -7 |
| o. Slapped another person | 1 | 2 | -4 | -7 |
| p. Kicked, bit, or hit someone | 1 | 2 | -4 | -7 |
| q. Hit or tried to hit anyone with something (an object) | 1 | 2 | -4 | -7 |
| r. Beat up someone | 1 | 2 | -4 | -7 |
| s. Threatened anyone with a knife or gun | 1 | 2 | -4 | -7 |
| t. Used a knife or gun on another person | 1 | 2 | -4 | -7 |

**LOGIC: IF NO MAIN SEXUAL PARTNER (L9=NO, DK/UNSURE, OR REFUSED) SKIP TO I3**

***Now I would like to ask you about things that your main sexual partner may have done to <u>you</u>. Let me remind you that this information will remain strictly confidential.***

I2. In the past 90 days, has your **main sexual partner**…?

**NOTE: READ LIST AND MARK A RESPONSE FOR EACH ITEM**

| | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|
| a. Abused you emotionally, that is, did or said things to make you feel very bad about yourself or your life | 1 | 2 | -4 | -7 |
| b. Attacked you with a gun, knife, stick, bottle, or other weapon | 1 | 2 | -4 | -7 |
| c. Hurt you by striking or beating you to the point that you had bruises, cuts, or broken bones, or otherwise physically abused you | 1 | 2 | -4 | -7 |
| d. Pressured or forced you to participate in sexual acts against your will | 1 | 2 | -4 | -7 |

I3. Has anyone <u>ever</u> physically hurt you (i.e., someone hurt you by striking or beating you to the point that you had bruises, cuts, or broken bones)?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED, SKIP TO I8.**

I4. **(HAND RESPONDENT SHOWCARD O-1)** When was the <u>last time</u> you were physically hurt?

Within the past two days.....1
3-7 days ago.....2
1-4 weeks ago.....3
1-3 months ago.....4
4-12 months ago.....5
More than 12 months ago.....6

DK/UNSURE.....-4
REFUSED.....-7

I4a. The <u>last time</u> you were physically hurt did you seek medical help?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

I4b. (**HAND RESPONDENT SHOWCARD O-2)** The last time you were physically hurt, who hurt you?

Main sexual partner.....1
Client.....2
Male relative .....3
Female relative.....4
Friend/acquaintance/peer .....5
Stranger (not a client).....6
Big mama or pimp .....7
Police.....8
Drug dealer.....9
Security guard .....10
OTHER .....99

**Specify:** _____

DK/UNSURE.....-4
REFUSED.....-7

I5. How old were you when you were first physically hurt?

AGE ..... |__|__|

DK/UNSURE..... -4
REFUSED..... -7

I5a. (**HAND RESPONDENT SHOWCARD O-2)** The first time you were physically hurt, who hurt you?

Main sexual partner.....1
Client.....2
Male relative .....3
Female relative.....4
Friend/acquaintance/peer .....5
Stranger (not a client).....6
Big mama or pimp .....7
Police.....8
Drug dealer.....9
Security guard .....10
OTHER .....99

**Specify:** _____

DK/UNSURE.....-4
REFUSED.....-7

I6. Have you ever gone to file a complaint to the police after you have been physically hurt?

YES .....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I8**

I7a. Was there a court case following your complaint to the police?

YES .....1

NO.....2

DK/UNSURE.....-4
REFUSED.....-7

I7b. Was there a conviction?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

I8. Has anyone ever pressured you or forced you to participate in sexual acts against your will?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED, SKIP TO I14**

I9. (**HAND RESPONDENT SHOWCARD O-1)** When was the last time you were pressured or forced to participate in sexual acts against your will?

Within the past two days.....1
3-7 days ago.....2
1-4 weeks ago.....3
1-3 months ago.....4
4-12 months ago.....5
More than 12 months ago.....6

DK/UNSURE.....-4
REFUSED.....-7

I9a. (**HAND RESPONDENT SHOWCARD O-2)** The last time you were pressured or forced to have sex, who pressured or forced you?

Main sexual partner.....1
Client.....2
Male relative.....3
Female relative.....4
Friend/acquaintance/peer.....5
Stranger (not a client).....6
Big mama or pimp.....7
Police.....8
Drug dealer.....9
Security guard.....10
OTHER.....99

**Specify:** _____

DK/UNSURE.....-4
REFUSED.....-7

I10. How old were you when you were first pressured or forced to have sex?

AGE ..... |__|__|

DK/UNSURE..... -4
REFUSED..... -7

I10a. (**HAND RESPONDENT SHOWCARD O-2)** The first time you were pressured or forced to have sex, who pressured or forced you?

Main sexual partner.....1
Client.....2
Male relative.....3
Female relative.....4
Friend/acquaintance/peer.....5
Stranger (not a client).....6
Big mama or pimp.....7
Police.....8
Drug dealer.....9
Security guard.....10
OTHER.....99

**Specify:** _____

DK/UNSURE.....-4
REFUSED.....-7

I11. Have you ever gone to file a complaint to the police after you have been pressured or forced to have sex?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I13a.**

I12a. Has there ever been a court case following your complaint to the police?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO I13a.**

I12b. Has there ever been a conviction?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

I13a. The last time you were pressured or forced to have sex did you seek medical help?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

I13b. The last time you were pressured or forced to have sex did you seek rape counseling?

YES.....1
NO.....2

DK/UNSURE.....-4
REFUSED.....-7

I14. Are you currently concerned that in the near future (or next 30 days) that someone might…?

**NOTE: READ LIST AND MARK A RESPONSE FOR EACH ITEM**

| | | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|---|
| a. | Attack you with a weapon | 1 | 2 | -4 | -7 |
| b. | Abuse you physically | 1 | 2 | -4 | -7 |
| c. | Make you engage in sexual acts against your will | 1 | 2 | -4 | -7 |
| d. | Abuse you emotionally | 1 | 2 | -4 | -7 |

***Now I want to ask you what you think about men's and women's roles.***

I15. **(HAND RESPONDENT SHOWCARD O-4)** Now I am going to ask you to respond to some statements about whether or not it is acceptable for a man to hit or beat a woman in a variety of circumstances. Please tell me how much you AGREE or DISAGREE with the following statements:

| | **Strongly Agree** ▼ | **Agree** ▼ | **Neither agree or disagree** ▼ | **Disagree** ▼ | **Strongly Disagree** ▼ | **DK** ▼ | **REF** ▼ |
|---|---|---|---|---|---|---|---|
| h. She does not complete her household work to his satisfaction. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| i. She disobeys him | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| j. She refuses to have sexual relations with him. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| k. She asks him whether he has other girlfriends. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| l. He suspects that she has been unfaithful. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| m. He learns that she has been unfaithful. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |
| n. She asks him to use a condom. | 1 | 2 | 3 | 4 | 5 | -4 | -7 |

**LOGIC: IF NO MAIN SEXUAL PARTNER (L9 = NO, DK/UNSURE, OR REFUSED) SKIP TO SECTION J**

I16. If you were having trouble with your main sexual partner, are any of the following "safe places" where you can escape…?

| | YES ▼ | NO ▼ | DK/ Unsure ▼ | REF ▼ |
|---|---|---|---|---|
| i. Your main sexual partner's family home. | 1 | 2 | -4 | -7 |
| j. Your family home. | 1 | 2 | -4 | -7 |
| k. House of friend/neighbor | 1 | 2 | -4 | -7 |
| l. Police. | 1 | 2 | -4 | -7 |
| m. Church/mosque (Place of worship). | 1 | 2 | -4 | -7 |
| n. Hospital. | 1 | 2 | -4 | -7 |
| o. Women's shelter. | 1 | 2 | -4 | -7 |
| p. Other, specify: _____ | 1 | 2 | -4 | -7 |

***Now I am going to ask you about things that may have happened between you and your main sexual partner in the past month.***

I17. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often have you and your main sexual partner argued or gotten in a verbal fight?

Daily or almost daily.....1
2 to 3 times a week.....2
1 time a week.....3
2 to 3 times a month.....4
1 time a month.....5
Less than 1 time a month.....6
Never.....7

DK/UNSURE.....-4
REFUSED.....-7

I18. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often has your drug or alcohol use caused problems between you and your main sexual partner?

Daily or almost daily.....1
2 to 3 times a week.....2
1 time a week .....3
2 to 3 times a month.....4
1 time a month .....5
Less than 1 time a month .....6
Never.....7

DK/UNSURE .....-4
REFUSED .....-7

I19. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often did your main sexual partner use alcohol to the point of intoxication?

Daily or almost daily.....1
2 to 3 times a week.....2
1 time a week .....3
2 to 3 times a month.....4
1 time a month .....5
Less than 1 time a month .....6
Never.....7

DK/UNSURE .....-4
REFUSED .....-7

I20. **(HAND RESPONDENT SHOWCARD O-5)** During the past 30 days, how often did your main sexual partner use drugs, including dagga or marijuana?

Daily or almost daily.....1
2 to 3 times a week.....2
1 time a week .....3
2 to 3 times a month.....4
1 time a month .....5
Less than 1 time a month .....6
Never.....7

DK/UNSURE .....-4
REFUSED .....-7

I21. At any time in the last 30 days, did your main sexual partner push you, grab you, shove you, or hit you?

YES .....1
NO .....2

DK/UNSURE .....-4
REFUSED .....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO O34**

I22. **(HAND RESPONDENT SHOWCARD O-6)** In the past 30 days when your main sexual partner did any of these things, how often did this happen after he/she had drunk alcohol or used drugs?

Always .....1
More than half the time .....2
Half the time .....3
Less than half the time .....4
Never .....5

DK/UNSURE .....-4
REFUSED .....-7

I23. In the last 30 days, did you push, grab, shove, or hit your main sexual partner?

YES .....1
NO .....2

DK/UNSURE .....-4
REFUSED .....-7

**LOGIC: IF NO, DK/UNSURE, OR REFUSED GO TO P1**

I24. **(HAND RESPONDENT SHOWCARD O-6)** In the past 30 days when you pushed, grabbed, shoved, or hit your main sexual partner, how often did this happen after you had drunk alcohol or used drugs?

Always .....1
More than half the time .....2
Half the time .....3
Less than half the time .....4
Never .....5

DK/UNSURE .....-4
REFUSED .....-7

**J. TREATMENT ACCEPTABILITY**

| **Treatment Acceptability and Adherence Scale** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|

| *Please respond to the treatment/intervention that you have received indicating your agreement with each of the below statements* | Strongly disagree | | | Neither agree nor disagree | | | Strongly agree | NA |
|---|---|---|---|---|---|---|---|---|
| 1. If I began this treatment, I would be able to complete it. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 2. If I participated in this treatment, I would be able to adhere to its requirements. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 3. I would find this treatment exhausting. | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |
| 4. It would be distressing to me to participate in this treatment. | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |
| 5. Overall, I would find this treatment intrusive. | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |
| 6. This treatment would provide effective ways to help me cope with alcohol use. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 7. I would prefer to try another type of psychological treatment instead of this one | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |
| 8. I would recommend this treatment to a friend with a similar problem i.e alcohol use. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| 9. If I began this treatment, I would likely drop out. | 7 | 6 | 5 | 4 | 3 | 2 | 1 | |

APPENDIX 7a

# RELEASE OF MEDICAL RECORDS FORM

Staff ID: |__|__|__|__|__|

Date |__|__| / |__|__| / |__|__|__|__|
DD MM YYYY

## Consent for the Release of Confidential Information

I, _____, authorise the FASD Prevention Study (MaRISA+ plus) staff (PIs: Dr. Yukiko Washio & Dr. Petal Petersen Williams) to disclose the following information to _____ for the purpose of referral treatment recommendation and/or other services.

I understand that my records are protected and cannot be disclosed without my written consent unless otherwise provided for in the law. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it (e.g., obtaining medical assistance) and that in any event this consent expires automatically one year from the date this release was executed as indicated below.

Name of Participant (Printed):

_____

Signature of Participant: _____

Date: |__|__| / |__|__| / |__|__|__|__|

**WITNESS (if client is illiterate):**

Name of Witness (Printed): _____

Signature of Witness: _____ Date: |__|__| / |__|__| / |__|__|__|__|

**The consent is valid for 365 days from the date it was signed.**

APPENDIX 7b

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes***

***PLEASE DO NOT USE FULL NAMES ANYWHERE ON THIS FORM***

PARTICIPANT ID:.....|__|__|__|__|

STAFF ID: .....|__|__|

DATE:..... |__|__| / |__|__| / |__|__|__|__|

DD MM YYYY

WHERE:_____

**Fetal/Birth/Neonatal Outcomes**

| | | | |
|---|---|---|---|
| 1. | Fetal/birth weight | | |
| 3. | Fetal/birth head circumference | | |
| 4 | Birth length (cm's) | | |
| 5. | Mother's weight at delivery | | |
| 6. | Pregnancy complications | Yes □ | No □ |
| 7. | If yes to #6, what pregnancy complications? | | |
| 8. | Delivery method | | |
| 9. | Gestational age | | |
| 10. | Apgar score | | |
| 11. | NICU admission | Yes □ Length of stay_____ | No □ |
| 12. | Fetal Alcohol Syndrome diagnosis | Yes □ | No □ |
| 13. | Re-hospitalization incident (Mother) | Yes □ | No □ |
| 14. | If yes to #13, what was the reason for the re-hospitalization? | | |
| 15. | Re-hospitalization incident (Infant) | Yes □ | No □ |
| 16. | If yes to #15, what was the reason for the re-hospitalization? | | |
| 17. | Infant health complications | Yes □ | No □ |
| 18. | If yes to #17, what infant complications? | | |

Hard copy checked by: Staff ID
Initials Date / /

## Appendix 8

# The MaRISA Plus (MaRISA+)
# Biological Form - Intake

Participant ID: |__|__|__|__|__|__|__| Date Seen: |__|__|/|__|__|/|__|__|__|__| Staff ID: |__|__|__|
DD / MM / YYYY

---

**1. What visit is this for this participant?**

[1] ☐ Intake Baseline 1 Month 2 Month 3- Month

## DRUG AND ALCOHOL USE

**2. Conducted urine testing for drug use?**

[1] ☐ Yes ➲go to **2B**
[2] ☐ No

**2A. If "No" urine drug testing, why not?**

[1] ☐ Testing kit not available
[2] ☐ Other [specify] _____

**2B. If "Yes", what were the results?**

[1] ☐ Positive
[2] ☐ Negative ➲go to **3**

**2C. If "Positive", for which drugs?**

[1] ☐ AMP (Amphetamine)
[2] ☐ MET (Methamphetamine)
[3] ☐ COC (Cocaine)
[4] ☐ THC (Marijuana)
[5] ☐ OPI (Opiates)
[6] ☐ Mandrax
[99] ☐ Other _____

**3. Conducted alcohol urine test?**

[1] ☐ Yes ➲ go to **3B**
[2] ☐ No

**3A. If No urine test, why not?**

[1] ☐ Instrument not working or not available
[2] ☐ Other [specify] _____

**3B. If "yes" what were the results?**

[1] ☐ Positive
[2] ☐ Negative

**TAKE A PICTURE OF DRUG AND ALCOHOL TEST RESULTS**

**Photo of drug and alcohol tests results attached?**
☐ **Yes**
☐ **No [specify reason not attached]** _____

## Appendix 9 MaRISA Plus:

## BIOLOGICAL FORM FOR BLOODWORK

PARTICIPANT ID: .....|__|__|__|__|__|__|__|__|__|__|
STAFF ID:..... |__|__|
SITE……|__|__|__|__|__|__|
DATE OF SPECIMEN COLLECTION: .....|__|__| / |__|__| / |__|__|__|__|
DD MM YYYY

TIME OF SPECIMEN COLLECTION: |__|__| / |__|__ (HH:MM)

DATE OF SPECIMEN SENT TO LAB: .....|__|__| / |__|__| / |__|__|__|__|

DATE OF LAB COMPLETION:.....|__|__| / |__|__| / |__|__|__|__|
DD MM YYYY

**1. What visit is this for?** *(Please tick only one answer)*

[1] ☐ BASELINE
☐ 1-MONTH CHECK-IN
☐ 2-MONTH CHECK-IN
☐ 3-MONTH CHECK-IN

**2. Conducted testing for alcohol metabolite (Peth)?**

[1] ☐ Yes, blood drawn Test results: _____
[2] ☐ No, not positive for PeTh [3] ☐ No, positive but refused testing
[4] ☐ No, Other: Specify_____

**Initials:** _____

# APPENDIX 10

***Adapting and testing behavioral intervention to prevent Fetal Alcohol Spectrum Disorders and adverse infant outcomes***

***PLEASE DO NOT USE FULL NAMES ANYWHERE ON THIS FORM***

PARTICIPANT ID:..... |__|__|__|__|

STAFF ID: ..... |__|__|

DATE:.....|__|__| / |__|__| / |__|__|__|__|

DD MM YYYY

WHERE:_____

*READ: Thank you for agreeing to talk with me about your experience with the MaRISA-plus programme. Now that you have completed the programme, we want to ask you some questions about your experiences about the service you received. The information you provide us with will help us improve the intervention.*

**Acceptability of Intervention Measure (AIM)**

The FASD Prevention Intervention meets my approval.

- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

2) The FASD Prevention Intervention is appealing to me.

- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

3) I like the FASD Prevention Intervention

- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree

- ☐ 4= Agree
- ☐ 5= Completely agree

4) I welcome the FASD Prevention Intervention
- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

**Intervention Appropriateness Measure (IAM)**

1) The FASD Prevention Intervention seems fitting.
- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

2) The FASD Prevention Intervention seems suitable.
- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

3) The FASD Prevention Intervention seems applicable.
- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

4) The FASD Prevention Intervention seems like a good match.
- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

**Feasibility of Intervention Measure (FIM)**

1) The FASD Prevention Intervention seems implementable.
- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

2) The FASD Prevention Intervention seems possible.

- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

3) The FASD Prevention Intervention seems doable.

- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

4) The FASD Prevention Intervention seems easy to use.

- ☐ 1=Completely disagree
- ☐ 2= Disagree
- ☐ 3= Neither agree nor disagree
- ☐ 4= Agree
- ☐ 5= Completely agree

**Study Experience**

A. What did you think about the questions that the MaRISA-Plus staff asked you before starting the programme (that is the screening questions about alcohol use and pregnancy?)

*Probe*

1. What about the number of questions?
2. Were there any questions that were difficult to answer?

B. From what they explained to you, how much do you think your *alcohol use* made it difficult for you to follow the programme?

C. What would you like to tell us about your experience of the programme?

*Probe*

1. What did you like most about the programme?
2. What did you not like about the programme?
3. Were their parts that were difficult to understand or did not work well?

D. What did you learn from the programme?

*Probe:*

1. Were there any new skills that you learned?

2. What new information did you learn?

E. Since you completed the programme, what (if any) changes have you been able to make in your life?
*Probe*

1. Can you describe anything that you are doing differently in your life?
2. How has the programme made a difference in your life?

F What did you think about providing urine samples for alcohol testing?

*Probe*

1. What was easy/difficult about it?
2. How easy was it to attend the clinic twice weekly to provide samples?

G What did you think about the financial rewards received for remaining abstinent?
*Probe*

1. Was it too much/too little?
2. Was it fair to not be rewarded or positive samples?
3. Are there alternative awards that you would have preferred?

H What did you think of the weekly text messages? What did you like the most? Is there anything you would have like to see changed?

*Probe*

1. Were they helpful?
2. Did they influence your behavior?
3. Did the messages add value to your life?

I. Do you have anything else to tell me about your experience of the programme?

*Probe:*

1. What, if anything would have made your experiences of this programme better?

**Ending Questions**

Our time is about up. You have provided us with a lot of information in this short amount of time. Thanks again for your time—we really appreciate all of your help.

***[Give a short oral summary of the key ideas that emerged from the discussion.]***

A. Is this an adequate summary of the things that we have discussed today?

B. Do you have any questions for us?

C. Do you have anything to add that we may have missed? _____

_____

# FACILITIES & OTHER RESOURCES

## Integration of Partnerships and Communication Plan

## SOUTH AFRICAN MEDICAL RESEARCH COUNCIL (SAMRC)

The SAMRC, is a well-established research organization with an existing infrastructure and staff who are highly experienced and successful on NIH funded-projects, and conducting randomized controlled trials with key populations, and other at-risk populations. The SAMRC has established links to the target communities and therefore is well suited to developing linkages and implementing this research. The SAMRC has highly knowledgeable staff and faculty to train staff on the study protocol, oversee the implementation of the protocol, provide high-quality data collection, and provide confidential and accurate data entry and storage. SAMRC faculty and staff have been working for many years in the local communities and with a range of health, substance use, and other service providers. SAMRC faculty and project staff expertise and relations with both local communities and service providers will facilitate participant recruitment and tracking of participants over the lifespan of this proposed study (see www.samrc.ac.za for more information).

### Response to COVID-19 Public Health Emergency.

The SAMRC is working with stakeholders in South Africa, including the National Department of Health and Department of Science and Innovation, to support research and the country's rapid response to the novel coronavirus (COVID-19) disease outbreak. The president of the SAMRC, Professor Glenda Gray, is the chair of the research committee in the newly formed Ministerial Advisory Committee on COVID-19, which consists of over 50 expert advisors who will provide guidance on critical health issues in attempts to prevent further spread of the virus (https://www.samrc.ac.za/news/samrc-president-chairs-research-committee-covid-19). The previous CEO of the SAMRC and director of an SAMRC extramural research unit, Professor Slim Abdool Karim, is the chief epidemiologist advising the south African Minister of Health and Mr Cyril Ramaphosa, the country's president, on the COVID-19 response (https://www.dailymaverick.co.za/article/2020-04-07-the-world-class-team-leading-south-africas-battle-against-covid-19/). The SAMRC continues to monitor the outbreak and is actively participating and supporting initiatives for the treatment, mitigation, and management of coronavirus and is strongly encouraging research that addresses COVID-19. In addition, the SAMRC has made funding available to focus on COVID-specific research. The SAMRC will be supporting global efforts against COVID-19 through surveillance of the disease. Funding of R8 million has been made available towards disease surveillance at five hospitals, with further funding of R5 million towards genomic sequencing at the National Institutes for Communicable Diseases. It is also planning to make additional funding available towards drug treatment trials. (https://www.samrc.ac.za/media-release/mobilising-resources-against-covid-19-pandemic). The SAMRC's COVID-19 research contributions are described at: https://www.samrc.ac.za/research-for-our-people/covid-19-research

### Organization and Staff

The SAMRC was established in terms of Acts of Parliament (No's 19 of 1969 and 58 of 1991). Its most important functions are "to promote the improvement of the health and the quality of life of the population of the Republic and to perform other such functions as may be assigned to the SAMRC by or under this Act." Such "improvement" was to be attained "through research, development and technology transfer." The affairs of the SAMRC are managed by a Board that determines the SAMRC's policies and objectives. The Board, appointed by the Minister of Health, consists of a Chairperson; between 12 and 14 members who have distinguished themselves in medical science or a related science; two additional members; and a President.

The SAMRC is a national organization with offices in Cape Town, Pretoria, Johannesburg, and Durban and rural offices in Hlabisa in KwaZulu-Natal province, the Eastern Cape, and Northern Cape provinces. In November 1997, the SAMRC was reviewed by an international panel as part of the national review of the

country's science and technology system commissioned by the Department of Arts, Culture, Science and Technology. This review noted that "The Medical Research Council is a national asset." The SAMRC supports a core of more than 900 scientists (with advanced degrees) plus several hundred technologists operating through 22 extramural units (based at universities and research centers) and 15 intramural research programs which are led by internationally recognized scientists and function as centers of excellence. The Alcohol Tobacco and Other Drug Research Unit (ATODRU) is one of these intramural programs. A total of 500 research projects are undertaken with approximately 100 new projects submitted every year; producing more than 800 peer-reviewed publications and multiple policy briefs and reports annually. The SAMRC also supports 300 scientists engaged in 300 3-year short-term research projects (self-initiated research), which constitutes a substantial investment in the building of research capacity and the development of science in the region.

## Laboratory and Other Facilities

The SAMRC owns large campuses in Cape Town (Medicina Campus with laboratory space at Tygerberg Academic Hospital and Delft), Pretoria, and Durban. The SAMRC also has research facilities in Johannesburg, Hlabisa (KwaZulu-Natal), Worcester (Western Cape), the Northern Cape, and the Eastern Cape.

### Office Space, Library and Other Resources

Office space is available at the MRC (Cape Town) campus and within ATODRU there is access to office space for fieldworkers, photocopying, scanning, and facsimile machines. Key personnel have their own offices equipped with computers connected to Internet services and printers, and updated software in place. ATODRU staff members also have access to an administrator and a contracts manager, and access to a shared seminar room. Staff members also have ready access to statistical support and analysis services provided by the SAMRC's Biostatistics division. Staff and students have library facilities with access to books, periodicals, and most major journals (paper and electronic) in the field. Interlibrary loan facilities are available. During office hours, library personnel are at hand to provide customized literature search services. There is also 24-hour remote Internet access to library resources. The project manager will have access to her own office and fieldworkers will have access to a shared office with computers and Internet connections where they will be able to upload data each evening. Within the ATODRU field site there is also a subzero freezer dedicated for the storage of biological specimens and a locked archive data storage room.

## Computing Facilities, Network, and Security

The SAMRC has an Information Technology Services Division (ITSD) that provides and maintains a relevant corporate IT infrastructure for the SAMRC in an efficient manner. The Division supports the SAMRC's voice, video, and data systems. Systems are available and monitored 24 hours a day, 7 days a week. The Division's areas of responsibilities include desktop support; wide area network support; local area network support; Internet access (including a wireless network); application and database hosting; e-mail support; disaster recovery planning; and IT training. ITSD provides a windows server-based network. Microsoft exchange servers are used for electronic messaging and scheduling. Microsoft SQL servers are provided for database applications. The ITSD administrative staff is professionally trained in the supported products, with several holding industry and manufacturer-specific certifications (e.g., Microsoft-certified professional and Microsoft-certified systems engineer). Further, the SAMRC has a well-resourced computer infrastructure, with high-speed lines linking the main campus and each of the other campuses and satellite (field) offices.

***SAMRC Workstations***: The workstation of the typical SAMRC employee is an Intel Pentium computer running Microsoft 2010 professional with the latest updates and patches. Workstations are connected to the SAMRC data network, giving the scientist access to all facilities and software described in this section. A variety of software is available for SAMRC scientists including the latest MS office suite of applications (Word, Excel, PowerPoint, Project, Access, Explorer, Outlook); statistical packages such as SPSS, STATA, and SAS and qualitative data analysis packages such as NVIVO and Q N*dist; and other utilities such as Adobe Acrobat, Zipcentral; and regularly updated antivirus software (McAfee), ACASI, and RECAP for data capture.

***Security:*** Microsoft Windows Server operating system supports several security features including: local desktop security (i.e., user identification and password required for access), lockout of account upon repeated

entry of invalid password, and Administrator-defined user groups. The SAMRC has good systems for password management to help maintain computer and network security: every username on all ITSD systems has an associated password, no records of passwords are generated, automated controls are in place to ensure password quality (e.g., minimum length), and there is an automatic periodic expiration of passwords. A complete backup of all files on every disk is written to tape weekly. Every business day, a differential backup is performed on all files created or modified since the last complete backup. In the event of a hardware or software failure, files can be restored to their status as of the time of the last differential backup. Tapes of complete backups are kept for about 3 months. CD-R drives and external hard drives are used for long-term data archiving.

***SAMRC Data Network***: The SAMRC's data network is a fully switched Ethernet-based network interconnecting all buildings on SAMRC's main campus and our other campuses (Pretoria, Durban, Hlabisa) and several other remote field locations. Remote offices are connected to the network via dedicated network circuits or via the Internet using Virtual Private Networks (VPNs). User authentication is required for all remote access to the network. The core of the SAMRC network is located in a computer room at each major SAMRC site (Cape Town, Durban, and Pretoria). This ensures that the same level of physical security, electrical power conditioning, environmental conditioning and monitoring is provided to the network equipment and servers. The network is automatically monitored for utilization and faults.

***Network Security:*** SAMRC has excellent network security. All traffic between the SAMRC network and the Internet passes through an Internet firewall that is a single connection point providing protection and monitoring to all systems connected to or accessing the SAMRC network. The firewall is programmed to determine whether network access in compliance with the SAMRC's network security policy and then allow or prevent access to the network. Web servers are placed behind load balancing devices which are configured to deny all traffic not specifically allowed according to their configuration. Only approved file types are allowed on the servers. Computer-based tools are used to detect and identify vulnerabilities on the SAMRC systems. If detected, these vulnerabilities can be corrected before they are exploited. A multilayered antivirus program is in place. All e- mail is scanned and anti-spam filters are in place. Security awareness articles are posted on the SAMRC intranet to ensure that staff members are informed about following security procedures.

**Security at physical facilities**: SAMRC has a keyless, disk-controlled access system on all buildings. Access is controlled 24 hours a day, 7 days a week. Closed circuit TV cameras monitor all entrances. The system monitors and limits access to the buildings and to the ITSD computer room. Access is granted on an individual basis and reports can be generated to review access patterns. Visitors are not permitted to the computer room. Security officers control access to the main gates of the campus and regularly patrol the campus grounds, checking if doors are locked. Continuous electrical service for the computer room is ensured through using uninterrupted power supplies (UPS) and generators. Adequate air conditioning, ventilation, and fire detection systems are also available in the computer rooms. Temperature and humidity are monitored and alarmed.

## The Alcohol, Tobacco and Other Drug Research Unit (ATODRU).

ATODRU is led by globally recognised researchers in the field of alcohol, other drug use and HIV. It has offices in Cape Town and Pretoria and clinical research sites in Delft and Worcester. Within ATODRU's clinical research site, there is a subzero freezer (-70 degree Celsius) dedicated for the storage of biological specimens- this will facilitate long-term storage of dried blood spot samples for analysis at the end of the project and in future. Currently the unit's active research projects span the causes, prevention of, response to and health impacts of alcohol, tobacco and other drug use. ATODRU's environment and resources bring numerous strengths to this application. First, it is a *well-established research unit* with an existing infrastructure and staff who are highly experienced and successful in collaborating with NIH-funded research, in clinical trials methodology and rigorous study design and in the conduct of trials. For instance, Dr. Nandi Siegfried, a global expert in clinical trials is part of ATODRU and works across projects to ensure that studies are designed and conducted to the highest standard. Second, the unit has *established links to the target communities* and therefore is well suited to conducting this community-based study. Third, the unit has *highly knowledgeable staff* and faculty to train staff on the study protocol, oversee the implementation of the protocol, provide high-quality data collection, and provide confidential and accurate data entry and storage. We have two dedicated data managers in the unit- one based in Cape Town and the other in Pretoria who will be able to ensure high quality data collection. Fourth, ATODRU has been working for many years in the local communities and with

a range of health, substance use, and other service providers. Dr. Petersen Williams has a *long-standing relationships* with the HIV, STI and TB service director of the Western Cape Department of Health and with the facility managers of primary care clinics and Midwife Obstetric Unit operational managers that provide antenatal care for our target communities and where study activities will take place. She will leverage these relationships to ensure by in from healthcare facilities and staff. The unit's excellent reputation will facilitate access to services and to routinely collected health service information.

All managerial responsibility and oversight will occur within ATODRU managed by Dr Petersen Williams. This includes site reporting, financial management, procurement of equipment and research supplies, and management of field activities.

## Administrative Information

SAMRC's mailing address is South African Medical Research Council, PO Box 19070, Tygerberg, 7505, South Africa. SAMRC's street address is 1 Duiker Street, Francie Van Zyl Drive, Parow, 7505, South Africa.

**Midwife Obstetric Units (MOUs) and Baby Clinics**

Within the Cape Town district, antenatal and postnatal care is provided at various primary care clinics, secondary and tertiary hospitals as well as at primary healthcare (PHC) facilities called Midwife Obstetric Units (MOUs). These MOUs provide primary obstetric care to women within defined areas (making them geographically accessible). MOUs are located within PHCs where baby clinics are co-located. There are 11 MOUs in greater Cape Town and all fall under the Western Cape Department of Health. They include: Bishop Lavis, Elsies River, Gugulethu, Hanover Park, Heideveld, Khayelitsha (Site B), Kraaifontein, Macassar, Khayelitsha (Michael Mapongwana), Mitchell's Plain and Retreat MOUs. All are found in areas that were classified as "Black African" or "Coloured" under the apartheid regime and given their location, the clientele visiting these clinics are mainly from these ethnic backgrounds. Furthermore, the MOUs can be considered as serving previously disadvantaged communities and the majority of women accessing these services continue to be disadvantaged. MOUs are birthing units run by midwives in the community for primary health care patients with doctors visiting these facilities once a week. Midwives routinely manage deliveries at these facilities and refer those who have high risk pregnancies to secondary or tertiary hospitals according to defined protocols. Post-natal care also takes place at these clinics. Referral to a hospital can occur at any stage, should this be necessary. The combined annual total number of women seen in the 11 MOU clinics during 2007 and 2008 was 41715. About 3% of these pregnant women attended the smallest clinic and 17% attended the largest clinic in the area. Most patients start their prenatal care at the beginning of the second trimester and are seen by their midwives monthly up to 32 gestational weeks and weekly or biweekly for the remainder of pregnancy. In order to conduct research activities in any of these facilities we will need to formally apply for approval from the Western Cape Department of Health who will liaise with facility managers about their willingness and ability to accommodate a research study before informing us which facility the proposed study can take place in. On average 83 new patients are seen at an MOU clinic per month.