

Attachment : Women's Health Needs Study Informed Consent to be a Research Participant

Women's Health Needs Study Informed Consent to be a Research Participant

My name is _____ and I am working with NORC and the Centers for Disease Control and Prevention on this study.

Why we are doing this study? We are trying to find out about the health care needs of women age 18 to 49 years in your community. We plan on interviewing about 100 women for this study.

Who is funding this study? This study is funded by the Centers for Disease Control and Prevention.

What would I be asked to do if I am in this study? The interview will take you about 45 minutes. We will read you the questions in your preferred language. We will be asking you some questions to see if you are eligible to be in the study. These will be about things like where you and your family are from, what languages you speak, and if you have lived in certain countries. If you are eligible, give consent, and then choose to enroll in the study, then we will be asking you questions such as how long you have been in the US, if you have had a medical exam, your childbirth experiences, and what you and your family thinks about female circumcision and your experiences with female circumcision. Some of the study questions may make you feel uncomfortable. You can skip any question. Your answers are completely private and only results from the whole group of women will be included in any report.

How long will it take for me to participate in this study? For this study you will do one interview that will take about 45 minutes to complete. This will end your time in the study.

Are there any risks for me if I decide to participate? The risks to participating in this research are minimal. However, some of the questions are personal and might make you uncomfortable. You are free to skip or not answer any questions. You can stop at any time. I have community resources available for you if you need help finding support or services in your community.

If you choose to do the survey whether you complete the survey or not, you will not lose access to any services that you would otherwise be eligible for. Your answers will be kept private to the extent allowed by law and will be used only for research. The study has a Certificate of Confidentiality, so no one outside the study, even an official of the court, the government or law, can request your information. However, if interviewers and other study staff learn of plans to have your minor daughter circumcised they may be legally obligated to report this as child abuse to state or local authorities. The study does not ask you about circumcision in your daughter.

Employees of CDC, or experts and contractors working for CDC, may review information sent through computer networks to assess security. We will not collect your name or other information that identifies you during this interview. When results from this research are presented, we will not include any information that might be used to figure out who you are.

Are there any benefits for me if I decide to participate? There is no direct benefit to you for participating in the study. We believe the answers you provide will help us better understand the health care needs of women in your community.

Payment for participation: If you agree to be in this study we will give you \$20 for your travel and/or child care expenses. In addition, if you recruit another women to be in this study, we will give you \$5 for cell phone calls and/or transportation. You may recruit up to 3 women and receive \$5 for each woman you recruit. You may need to contact these 3 women with our study invitation card. You will be able to receive a total of \$35 reimbursement for expenses you may need to participate in the study and for recruiting up to three women.

A unique passcode will let us know which women you helped recruit so that we can reimburse you. Your name will not be collected at any time during this study.

Do I have to be in this study? No you do not. If you choose to be in this study, you can stop at any time and you are also free to skip or not answer any questions.

What happens if I would like to stop this interview? If you start the interview and decide to stop, that is perfectly OK. You will still receive the \$20 for your travel and/or any child care expenses you may have during this interview. We will be able to keep and use the information you have shared up until that point. If you do not want your responses to be included, let us know and we will destroy your information.

Right to Ask Questions: Please contact Field Coordinator at (XX) with questions, complaints or concerns about this research. If you have any questions or concerns about your rights as a research participant, please contact the NORC IRB Manager by toll-free phone number at (866) 309-0542. An Institutional Review Board (**IRB**) operates under Federal regulations and they review research involving human subjects to ensure the ethical, safe, and equitable treatment of study participants.

Do you have any questions about this study? If you have any questions or concerns regarding this study please ask. If you think of them later, contact the study number at 866-315-7130.

What if I do not want to be in this study? If you do not wish to participate, we sincerely thank you for your time.

If you would like to participate: You must be 18 to 49 years of age to take part in this research study.

Participation in this study implies that you have reviewed and understand what is being asked of you for this study and that you are voluntarily willing to take part of this study. Your answers will be private and you can stop at any time.

Would you like a copy of this form?

Attachment : WHNS Informed Consent Observation Form

Date: _____ / _____

Respondent ID: _____

Interviewer ID: _____

Language Used: _____

Respondents' Experience with the Informed Consent Statement

Topics of Informed Consent

- Study Objectives
- Risks to respondents
- Benefits to respondents
- Voluntary participation
- Confidentiality
- Reimbursement
- Who to ask if you have questions

Comments on Interaction

Decision of respondent

Wants to participate: yes/no

Does not want to participate: yes/no

Wants more information: yes/no

Reaction of respondent

Attention of respondent:

- Pays no attention
- Pays a little attention
- Pays close attention

Respondent asks questions: yes/no

Respondent Questions

Did you avoid using medical terms and scientific jargon that the participant clearly does not understand, and did you communicate using understandable language?

Presentation of Consent Form