Parent participant informed consent form

Study Title: "Knowledge assessment of women of reproductive age on birth defects: A cross-sectional study in Kenya"

Introduction

I, **George, N. Agot,** as the Principal Investigator, along with **Prof Joseph, K. Wang'ombe, and Dr. Marshal, M. Mweu** as Co-Investigators, would like to tell you about a study being conducted by the above-listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles that apply to all participants in medical research: (i) Your decision to participate is entirely voluntary (ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal (iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? Yes / No

This study has been approved by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee: **Protocol No. Ref: KNH-ERC/A/44**

What is this study about?

Participants in this research study will be asked questions about knowledge of birth defects. We are asking for your consent to consider participating in this study.

What will happen if you decide to be in this study?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions, and the interview will last approximately 10 minutes. After the interview has finished, if you require counseling, I will provide a trained counselor in a private and comfortable room for you. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include clarifying some of the information you will have given and not clear to me.

Are there any risks, harms, or discomforts associated with this study?

Medical research has the potential to introduce psychological, social, emotional, and physical risks. Efforts will always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a coded number to identify you in a password-protected computer database and will keep all our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be fully secure, so it is still possible that someone could find out you were in this study and could find out information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse to participate in the interview or any questions asked during the interview. It may be embarrassing for you to ask some questions; however, we will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, some information about the child may be stressful and not easy to recall, however, I request you provide the most correct responses to the best of your ability.

Are there any benefits to being in this study?

You may benefit by receiving free counseling when needed and health information, as necessary. We will refer you to a hospital for care and support where necessary. This information is a contribution to science and policy formulation on the prevention, control, rehabilitation, and treatment of children born with birth defects.

Will being in this study cost you anything?
Not at all, you will not be asked to pay anything for participating in this study and you will not be refunded any money for participating in this study.

What if you have questions in the future?
If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your rights as a research participant, you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Extension 44102, and email address: uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

What are your other choices?
Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Participant's statement
I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study. I understand that all efforts are made to keep information regarding my identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: **Yes / No**
I agree to provide contact information for follow-up: **Yes/No**
Participant Printed Name: _____
Telephone Number: _____
Participant Signature / Thumb Stamp: _____**Date** _____
Researcher's statement
I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant understood and has willingly and freely given his/her consent.

Researcher's Name: _____**Date:** _____

Signature: _____

Role in the study: _____ [i.e., study staff who explained the informed consent form.]

For more information contact 0721589544 at any time from 8.00 am to 5.00 pm