FHI 360

Informed Consent Form (Uganda) // In-depth Interview

Title: Market Research on Service Delivery Implications for a 4-month Depot Medroxyprogesterone Acetate Subcutaneous (DMPA-SC) Product

Protocol Number: 1659914

Sponsor: Children's Investment Fund Foundation (CIFF) and USAID

Principal Investigator:

Address: FHI 360,

Site(s):; Uganda ::; Nigeria

Study Related Phone Numbers: [Uganda;
Nigeria;]

Introduction

Good Morning/Afternoon. My name is _____ and I work for/am working with FHI 360. This study is about DMPA-SC and other injectable contraceptive methods. The research is funded by the Children's Investment Fund Foundation (CIFF) and the US Agency for International Development.

This consent form contains information about the research study. I am going to read and explain the form to you so you can decide if you want to participate. This form might contain some words that are unfamiliar to you. Please ask me to explain anything you do not understand, you can ask questions at any time.

Information about Taking Part in this Research Study

You are being asked to participate because you have been identified as a key informant based on your experience with the introduction or scale up of depot medroxyprogesterone acetate subcutaneous or DMPA-SC in [Uganda/Nigeria].

Preliminary data from a recent clinical trial suggest that Sayana Press is safe and effective when injected every 4 months. The purpose of this study is to assess key informant perspectives on the potential health system implications of introducing a new 4-month DMPA-SC product in [Uganda/Nigeria]. We would like to talk with you about your thoughts on how such a product might

be received and implemented in [Uganda/Nigeria]. We would also like to ask you some questions about a potential six-month injectable product which is currently in development.

In addition to interviews with key informants, we will also conduct a focus group discussion with members of DMPA-SC working groups/committees in [Uganda/Nigeria] as well as small group discussions with clinic providers and [VHTs/CHEWs]. Information learned in this study may be used to guide introduction and implementation of a 4-month DMPA-SC product in [Uganda/Nigeria]. Study results may also be used to inform the introduction of future injectable contraceptives in [Uganda/Nigeria] and possibly elsewhere.

Type of Research

If you choose to participate in this research, I will ask you questions about the:

- Possible benefits and risks of introducing injectable contraceptives of varying durations;
- Potential implications for service delivery including training and logistics with the introduction of new injectable products; and
- Potential implications for clients and the kinds of information they may require with new injectable products.

I will audio-record the discussion which will last about one hours (60 minutes).

Possible Risks

The risks to you of participating in this interview are low. However, you will be one of a limited number of individuals who will be asked to take part. It is possible that, by deduction, others can guess that you participated in this study. You can decide what information you would like to share with us. You can skip any question you do not want to answer. You may stop participating in the interview at any time.

<u>COVID-19 Mitigation Plan</u>

To reduce the risk of study participants' exposure to COVID-19 as much as possible, the Key Informant Interviews will be virtual whenever possible and conducted via Zoom or Teams, especially for participants in the cities. Where the interview has to be physical, the interviewer and participant will each sterilize or wash hands before the interview, maintain safe social distance and wear masks throughout the length of the interview. At the start of the interview the investigator will check to see that all the necessary pre-conditions set out as part of the mitigation plan are in place and adhered to.

Possible Benefits

There are no direct benefits to you for taking part in this interview. However, information learned in this study may be used to guide implementation of an extended duration recommendation for DMPA-SC in [Uganda/Nigeria].

Voluntary Participation
Taking part in this research study is voluntary. You are free to decide if you want to be in this research. If you choose not to take part in this research, there will be no penalty to you, and it will not affect your employment.

Confidentiality
We will do our best to protect information about you and your participation. We will conduct the interview in a private location. We will use a participant number instead of your name. We will remove any reference to your name or anyone else you mention when we write the notes from the audio recording. We will not use your name in any report. We will ensure that any information we include in reports does not identify you.

Any study information collected in paper form will be kept in a locked file cabinet. Computer data will be password protected and only study staff will have access. The audio-recording will be destroyed after the completion of data analysis. The information you provide may be used for future research studies or shared with another researcher for future research studies without asking you for your consent again.

Payment
There are no costs to you for participating in this study other than the time you will spend in the interview. You will receive [the local currency equivalent of 25 USD: roughly 92,570 Ugandan shillings/9575 Nigerian Naira] as compensation for expenses you may incur because of participating in the study, such as travel cost.

If You Have a Questions About the Study
If you have question about this research, contact site investigator

This research has been reviewed and approved by

I will give you a copy of this form for your information. Do you have any questions for me about this study or your participation?

CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions and all of my questions been answered to my satisfaction. I consent voluntarily to be a participant in this study. I understand that the discussion will be audio-recorded.

[Participant should tick appropriate box below]

I consent voluntarily to be a participant in this study	YES ☐	NO ☐
I consent to be audio recorded	YES ☐	NO ☐

_____ _____

Signature or mark of participant Date

Statement by the researcher

I certify that the nature and purpose, the procedures, the potential benefits, and possible risks associated with participating in this research have been explained to the participant, and she/he has provided consent to take part in the focus group discussion.

Print Name of Researcher _____

Signature of Researcher _____

Date _____

Day/month/year