FHI 360

Informed Consent Form (Uganda) // Focus Group Discussion
Clinic-based Providers & Community Health Workers (CHWs)

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):

Study Related Phone Numbers:

Introduction
Good Morning/Afternoon. My name is _____. I am a researcher and I work with/for FHI 360 on this study about DMPA-SC and other injectable contraceptive methods. This research is funded by the Children's Investment Fund Foundation (CIFF) and the US Agency for International Development (USAID). We are inviting you to participate in this research study. We want you to understand the purpose of this research and your role so you can decide if you want to join.

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:

1. You are a [CHW (VHT member / CHEW) **or** clinic-based provider] from one of the facilities selected for this study
2. You have given DMPA-SC in the past 3 months

Early data from a recent FHI 360 study suggest that depot medroxyprogesterone acetate subcutaneous or DMPA-SC is safe and effective if injected every 4 months. We would like to talk with you about how a new 4-month DMPA-SC product might be received and provided in [Uganda /

Nigeria]. We would also like to ask you some questions about a potential six-month injectable which is currently in development.

We are conducting two small focus group discussions with [VHTs / CHEWs]. We will also speak with other providers and policy makers. The information we learn in this study may be used to guide the introduction of a 4-month DMPA-SC product in [Uganda / Nigeria]. Information learned may also be used to inform the introduction of future injectables in [Uganda / Nigeria].

Type of Research
If you choose to participate in this research, I will ask you questions about:

- What introducing a new injectable that prevents pregnancy for 4 months would mean.
- How best to include this product into the FP service delivery system in [Uganda / Nigeria].
- Risks and benefits of having several types of injectables in [Uganda / Nigeria]; and
- Potential reactions from clients to this new product.

I will audio-record the focus group discussion. The discussion will last about one and a half hours (90 minutes).

Possible Risks
The risks involved in this focus group discussion are low. It is possible that someone could guess that you took part 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 the being in the focus group discussion at any time.

I will give you a copy of this form, but you do not have to take the copy. It is possible that having a copy of the form will show others that you were associated with this project.

<u>COVID-19 Plan</u>
To reduce exposure to COVID-19, focus group discussions will be physical or virtual. This will depend on local guidance and participant preference. A room in a hotel or similar private, quiet setting will be used to host no more than 3 participants. All will maintain social distancing and wear masks throughout the discussion. The investigator will check to see that all the conditions of this plan are followed.

Possible Benefits
There are no direct benefits to you for taking part in this focus group. However, information learned in this study may be used to guide introduction of 4-month DMPA-SC product 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. Choosing not to participate will not affect your position as a [CHW **or** clinic-based provider].

Confidentiality
We will do our best to protect information about you and your participation. We will conduct the focus group in a private location. We will ask everyone in the focus group to keep the privacy of the other participants. However, it is possible other people in your group discussion could share information about you with others outside the group. We cannot guarantee the other people will keep the discussion private. The groups will be audio recorded with voices only. We will take out your name or anyone else you mention when take notes. We will not use your name in any reports.

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. Information you provide could 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 focus group. You will receive [the local currency equivalent of 25 USD: roughly 92,570 Ugandan shillings/9575 Nigerian Naira] plus a small refreshment 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 the Institutional Review Board of

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