FHI 360

Informed Consent Form (Uganda) // Focus Group Discussion
DMPA-SC Stakeholders

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 _____ and I work for/am working with FHI 360. 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).

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 conducted by FHI 360 suggests that DMPA-SC 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.

We are conducting a focus group discussion with members of the DMPA-SC [Task Force in Uganda/**TBD** Nigeria]. We will also conduct in-depth interviews with about 20 other individuals who have been involved in the introduction or scale up of DMPA-SC 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 in [Uganda/Nigeria]. Information learned 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 and a half hours (90 minutes).

Possible Risks

The risks involved in this focus group discussion 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 focus group discussion at any time.

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

To reduce the risk of study participants' exposure to COVID-19 as much as possible, focus group discussions will employ both physical and virtual formats such as Zoom or Teams. A room in a hotel or similar private, quiet setting with clearance to accommodate physical meetings will be procured to host a small number of participants (no more than 10) who will maintain social distancing and also wear masks throughout the length of the discussion. At the start of the FGD 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 focus group. 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

There is the potential risk of breach of confidentiality if someone guessed that you had participated, however we will do our best to keep your personal information confidential and ask you, and all participants, not to share with others information about our conversations during our group discussions. However, this cannot be guaranteed. We will report the information you share with us as a summary instead of using your exact words and will not include any identifying information such as names or other specific details 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 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 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

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