

INDIVIDUAL INTERVIEWS INFORMED CONSENT

1. PURPOSE

This document describes the process by which DeWorm3 study staff obtain informed consent from eligible participants after they have been provided all necessary information about the study.

2. INTENDED USERS

Implementation science teams and qualitative researchers.

3. RESPONSIBILITIES

All DeWorm3 study staff should understand and follow this SOP during the consenting and enrollment of study participants during qualitative research. It is the responsibility of the site's Principal Investigator to ensure that all study staff comply with this SOP during consenting of study participants to participate in qualitative research activities.

4. DEFINITIONS

4.1. **Consent Form:** A document that describes study related procedures to eligible participants. This form should disclose the risks and benefits of study participation so that potential participants can make an informed and voluntary choice regarding their participation in the study. Consent is provided by signature or a thumbprint verified in the presence of a witness.

5. REQUIRED MATERIALS

- 5.1. Study staff ID and introduction letter
- 5.2. Study information sheets in local language
- 5.3. Qualitative research consent forms in local language
- 5.4. Clipboard and black pen
- 5.5. Ink pad, and wiping cloth
- 5.6. Binder or folder for filing all completed qualitative research consent forms

6. PROCEDURE

- 6.1. At the beginning of interviews, study staff will determine which language the individual prefers and whether the individual can read and write. If the individual is illiterate, then an impartial witness, an adult of the participant's choice (not study staff), should be selected and they should sit through the entire consenting process.
- 6.2. Using the provided study information sheets, study staff will verbally explain to the potential participant the purpose of the research and the risks and benefits of study participation.
- 6.3. Potential participants will be told that participation in the research is completely voluntary and if they do not feel comfortable, they need not participate. It should be clear to the participant that they are consenting to participate and be audio recorded, but their identity will remain anonymous.
- 6.4. If the potential participant is interested in participating in the qualitative research and is able to read, she/he will be given a Consent Form in their preferred language to review.
- 6.5. Study staff will read the Consent Form aloud to the potential participant.
- 6.6. After the study staff and the participant have read through the entire Consent Form together, the study staff will answer any questions that the potential participant has regarding the study or study participation.
- 6.7. If the potential participant agrees to participate in the qualitative research, the study staff will provide two copies of the Consent Forms for him/her to sign.
- 6.8. After the potential participant provides consent, the study staff must countersign both Consent Forms. One copy should remain with the participant and study staff will keep

the other copy.

- 6.9. If the potential participant is unable to sign the Consent Forms, she/he will apply a thumbprint using the inkpad. However, her/his name must be written on the same page by the impartial witness.
- 6.10. If the potential participant is reluctant to sign the Consent Form, then the study staff should ask her/him if she/he has questions that need to be clarified.
- 6.11. If the potential participant indicates unwillingness to participate in the study, then the study staff will thank her/him for the time and assure him/her that this will not affect their access to MDA or other health services in the future.

Current Document			
Version No.:	1		
Developed by:	Arianna Means	Date:	29 November 2016
Reviewed by:	Fabian Schaer	Date:	6 January 2017
Effective Date:			
Approvals			
<i>I have reviewed and approve this SOP for implementation.</i>			
Principal Investigator	Signature	Date	
Site Principal Investigator	Signature	Date	

Document History		
Version No.	Effective Date	Author(s)
1		Arianna Means



SITE NAME
Read and Review Log
List of individuals who read and reviewed the SOP

Date	Name	Title	Signature*

*By signing this log, study staff confirm that they have read and understood the content of the SOP