FOCUS GROUP DISCUSSIONS 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 focus groups. 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.

4.2. **Assent Form**: A document used for eligible children who are 7-15 years of age that describes study related procedures and records acknowledgement of willingness to participate by the child. These potential participants are too young to give informed consent but can understand the proposed research, possible risks/benefits, and activities expected of participants. If assent is provided, informed consent must still be obtained from the subject's parents or guardian (i.e. caregiver).

4.3. **Child:** Individual 12- 15 years of age (age of child participants in focus groups)

4.4. **Adult:** Individual 18 years of age or older (age of adult participants in focus groups)

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. Qualitative research assent forms in local language
5.5. Clipboard and black pen
5.6. Ink pad, and wiping cloth
5.7. Binder or folder for filing all completed qualitative research consent forms

6. PROCEDURE

6.1. With the exception of one focus group (conducted in four intervention clusters), all of the research participants will be adults. Caregivers must accompany children during the consenting process of the children's focus group.

Consent of adults and caregivers of children

6.2. At the beginning of focus groups, study staff will determine which language the potential participants or their caregiver prefers and whether the potential participants /caregiver can read and write.

6.3. Using the provided study information sheet, study staff will verbally explain to the potential participants and/or their caregivers the purpose of the research and the risks and benefits of study participation.

a. Consent and Assent Forms can be read to the entire group of potential participants at once.

6.4. Potential participants/caregivers will be told that participation in the research is completely voluntary and if they do not feel comfortable, they need not participate.

6.5. It should be clear to the potential participant that they are consenting to participate and be audio recorded, but their identity will remain anonymous.

6.6. If the potential participant or their caregiver is willing to participate in the qualitative research and is able to read, she/he will be given a Consent Form in their preferred language to review.

6.7. Study staff will read the Consent Form to the potential participant/caregiver.

6.8. After the study staff and the potential participant/caregiver have read through the entire Consent Form together, the study staff will answer any questions that the participant/caregiver has regarding the study or study participation.

6.9. If the participant/caregiver agrees to participate in the qualitative research, the study staff will provide two copies of the Consent Forms for him/her to sign.

Assent of children

6.10. If the participant is a child 12 to 15 years of age (the age range of child participants in focus groups), study staff will read the Assent Form to the participant. After reading the form, study staff should answer any questions that the child has.

6.11. If the child agrees to be in the study, the study staff will provide two copies of the Assent Forms for him/her to sign.

6.12. After the 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. One copy of the Assent form should be kept by the child's caregiver.

Impartial witness

6.13. If the participant and/or caregiver is unable to sign the Consent or Assent Forms because of illiteracy, she/he will apply a thumbprint using the inkpad. However, her/his name must be written on the same page by an impartial witness. The impartial witness must be an adult of the participant/caregiver's choice (not study staff) who has sat through the consenting process.

Unwillingness to participate

6.14. If the potential participant/caregiver is reluctant to sign the Consent or Assent Form, then the study staff should ask her/him if she/he has questions that need to be clarified and clarify them.

6.15. 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 have reviewed and approve this SOP for implementation.

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