

CENSUS 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

The intended users of this SOP are the trial coordinator, supervisors, census teams (enumerators), and other relevant DeWorm3 staff members.

3. RESPONSIBILITIES

All DeWorm3 study staff should understand and follow this SOP during the consenting and enrollment of study participants during censuses. It is the responsibility of the site's Principal Investigator (PI) to ensure that all study staff comply with this SOP during consenting of households when administering the census survey.

4. DEFINITIONS

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 if illiterate.

4.1. **Structure:** A building constituting a single, in the case of a house, or multiple residences, in the case of an apartment building.

4.2. **Compound:** A group of houses, generally found in a rural setting

4.3. **Household:** A person or group of persons who consider the house their permanent residence, who acknowledge one adult male or female as the head of household and who share a cooking pot. A household member may travel for work or education, but regularly returns to the household as their primary permanent residence.

4.4. **Household ID Barcode:** A seven-digit unique ID assigned to each household during the census. The household ID is encoded within a barcode/QR and printed on a sticker. For the census, there will be four barcode stickers printed for each household. Each of the four barcode stickers has the same household ID but with a different label for the corresponding step of the consent process: (i) **study** for the Office Copy of the Consent Form; (ii) **hhold** for the Household Copy of the Consent Form (iii) **icard** for the Study Identification Card (iv) **extra** to act as a spare in case one of the others is spoiled.

5. REQUIRED MATERIALS

5.1. Study Staff ID and Introduction Letter (available with the supervisor and obtained if needed)

5.2. Study Information Sheets, in local language

5.3. Census Consent Form in local language

5.4. Clipboard and black pen

5.5. Ink pad

5.6. Binder or folder for filing all completed Census Consent Forms

5.7. Four Barcodes per household

5.8. Study Identification Cards

5.9. Sharpie or other permanent marker

5.10 Smartphone programmed with census

6. PROCEDURE

6.1. Approaching the household

- a. On reaching a structure, enumerators will confirm whether any household members are present. If so, the enumerators will greet the household members and establish whether there is an adult (aged 18 years or above) who is able to provide consent for the entire household.
- b. **If the head of household or alternative adult household member *is not present*** to participate in the census or if the household members would like to participate at a different time, the enumerator should schedule a time to return to complete the census. Before leaving the structure, the household ID barcode labelled “study” should be attached to an unsigned Census Consent Form – indicating there was nobody present/able to provide consent. This Census Consent Form will be placed in the binder to be taken back to the office and should have the name with which to locate the household and/or household head name to re-identify the household when returning later. This identifying information will be sought from any present household members, the village guide or a neighbour. Scan the household ID barcode on the form when prompted by the SurveyCTO Census Form. See [*SOP_202. Administering the baseline census*](#) for more details on this procedure
- c. **If the head of household or alternative adult household member *is present*** and able to provide consent and answer census questions on behalf of their household, affix matching household ID barcodes on two Census Consent Forms. Use the Household ID barcode labelled “study” for the copy of the Census Consent Form to be returned to the office and the barcode sticker labelled “hhold” for the copy to be left with the household. Scan the household ID barcodes on both forms when prompted by the SurveyCTO Census Form.

6.2. The consent procedure

- a. A household is defined as: a person or group of persons, related or unrelated, who consider the house (structure) their permanent residence and are affected by the decisions of the head of household. A household member may travel for work or education, but regularly returns to the household/house as their primary permanent residence.
- b. An adult household member cannot provide consent or census responses for another household.
- c. At the beginning of the visit, enumerators will determine which language the adult household member prefers and whether the individual can read and write. If the individual cannot read and write, an impartial adult will need to be available to sit in the consent process and act as a witness.
- d. Using the provided script, enumerators will verbally explain to the adult household member the purpose of the census.
- e. The adult household member will be told that participation in the study is completely voluntary and if they do not feel comfortable, they need not participate.
- f. If the adult household member is willing to participate in the census and is able to read, she/he will be given an Information Sheet and a Census Consent Form in their preferred language to review (these may be printed double sided on the same sheet).
- g. The enumerator will read the Census Consent Form to the adult household member.
- h. After the enumerator and the adult household member have read through the entire

Census Consent Form together, the enumerator will answer any questions that the adult household member has regarding census participation.

- i. If the adult household member agrees to participate in the census, she/he will be invited to sign the Census Consent Form.
- j. After consent is provided, the enumerator counter signs the Census Consent Form.
- k. If the adult household member is unable to sign the Census Consent Form, she/he will apply a thumbprint using the inks pad. However, a literate impartial witness, should be an adult of the participant's choice (not the enumerator) who has sat through the consenting process and will also sign their own signature on the consent form.
- l. The enumerator will provide two copies of the Census Consent Form for the adult household member to sign (both will have identical household ID stickers on them). The participant will be offered the copy with the "hhold" ID barcode on and the other copy with the "study" ID barcode on will be kept by the enumerator and placed in the binder or folder to return to the office.
- m. If the potential participant is reluctant to sign the Census Consent Form, then the enumerator will ask her/him if she/he has questions that need to be clarified.
- n. If the potential participant indicates an unwillingness to participate in the census, then the enumerator will thank her/him for the time and assure him/her that this will not affect their access to mass drug administration in the future.
- o. If the participating adult does not provide consent, then enumerator will record that consent was not received on an unsigned Census Consent Form (which will be returned to the office) and move on to the next household.
- p. The adult who consented should be given a Study Identification Card for the household. Before providing this card to the participating adult, the enumerator will write the name of the household head. The enumerator will select the matching barcode to the one placed on the consent forms for that household and place it on the Study Identification Card.

6.3. Use of the Census Consent Forms

- a. The Census Consent Form is to be used for all households visited during the Baseline Census.
- b. During the Census Update in subsequent years, all households who signed the Census Consent form at baseline (households should have a Study Identification Card and/or a signed Census Consent Form and the Study Staff will have a filed signed Census Consent Form in the consent binder) do not need to sign another Census Consent Form, even if new members need to be added to the household at the Census Update.
- c. If a new household is identified during the Census Update and they have never been previously consented to participate in the Census Survey, the field officer will need to conduct the procedures detailed in sections 6.1 and 6.2 in full.

6.4. Filing of the study copies of the Consent Forms

- a. The copies of the consent forms with the "study" household ID barcode on returned with the enumerators in the binder should be filed safely in the office.
- b. These will be required for other DeWorm3 activities, including census updates.

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| <i>I have reviewed and approve this SOP for implementation.</i> | | | |
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| Document History | | | |
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