

## **ADMINISTERING THE BASELINE CROSS-SECTIONAL SURVEY**

---

### **1. PURPOSE**

This document describes the process by which DeWorm3 study staff will administer the first cross-sectional survey to eligible participants. This survey should be administered only after the DeWorm3 study staff receive the consent or assent of participants. Two further cross-sectional surveys will be conducted over the five-year study period, but the random selection will be performed again for these surveys.

### **2. INTENDED USERS**

All DeWorm3 staff; including field managers, field supervisors and field officers, who will be planning, overseeing and/or administering the baseline cross-sectional surveys in the all intervention and control clusters.

### **3. RESPONSIBILITIES**

All DeWorm3 study staff should understand and follow this SOP prior to conducting the baseline cross-sectional survey. It is the responsibility of the site's Principal Investigator (PI) to ensure that all study staff comply with this SOP during the consenting of study participants who have been deemed eligible on the basis of the Screening/Eligibility criteria and the administration of the baseline cross-sectional survey.

### **4. DEFINITIONS**

**4.1. Cross-sectional survey:** A research method in which data are gathered to determine the prevalence of disease in a defined population at a particular point in time.

**4.2. Cross-sectional Survey Participant Sample List:** A list of 500 individuals from each cluster who are targeted to answer the questionnaire and provide a stool sample. The sample will be a random sample, proportional to the population.

**4.3. Cross-sectional Replacement Sampling Lists:** A set of five lists of reserve individuals from each cluster who may be approached for inclusion in the cross-sectional survey in the event that individuals from the cross-sectional survey participant sample list are unavailable, ineligible or unwilling to participate.

**4.4. Exclusion criteria** are conditions which prevent participation in the Cross-sectional Survey. Exclusion criteria include: individuals who cannot be confirmed as living in the study clusters; adults who do not provide informed consent, or children 7 years and above who refuse assent

### **5. REQUIRED MATERIALS**

**5.1.** Smartphone preloaded with SurveyCTO Cross Sectional Survey Form

**5.2.** Cross sectional survey participant sample list

**5.3.** Study Information Sheets, in local language

**5.4.** Cross sectional survey consent form in local language

**5.5.** Cross sectional survey assent form in local language

**5.6.** Clipboard and black pen

**5.7.** Ink pad, and wiping cloth

**5.8.** Binder or folder for filing all completed consent and assent forms

**5.9.** One barcode per individual

**5.10** Coloured dot stickers / various colour permanent marker pens

**5.11** Stool collection instructions

**5.12** Stool Collection Kits (newspaper, tissue roll, stool container, wooden sticks, bag)

**5.13** Permanent ink marker

**5.14** Latex gloves

## **6. PROCEDURE**

### **6.1. Survey preparation**

- a) The baseline Cross-sectional Survey will be conducted after or alongside the baseline Longitudinal Monitoring Survey.
- b) A population proportional sample of 500 randomly selected individuals of all ages will be invited to participate in this Cross-sectional Survey in each of the 40 clusters.
- c) In advance of the Cross-sectional Survey, the site coordination team should conduct a sensitization visit or phone call to village leaders to ensure that they are aware of the survey in advance of the survey team's visit.
  - i. During the sensitization meeting/call, the survey coordinator should state the purpose of the survey and discuss an optimal day or time for the survey team to start the visits in order to maximize participation.
- d) Prior to conducting the survey, the trial coordinator should ensure that the teams have the Cross-sectional Survey Participant Sample List. They will only be given the Cross-sectional Replacement Sampling List after all individuals in the original list have been visited three times and a survey has been logged for all 500 original participants.
- e) If required, the field supervisors should arrange for a village escort to be available to walk with the field officers during the survey and take them to the households to re-introduce them.
- f) Stool-collection kits should be prepared in advance so that these can be ready to be picked up and taken to the field in the morning (approximately 15 kits per field officer per day). To prepare the kits:
  - i. Cut the newspaper into pieces of approx. 7x7cm
  - ii. Tear off the tissue roll, counting several squares per kit
  - iii. Include a wooden spatula/stick
  - iv. Include a stool container
  - v. Compile each kit in a small opaque bag.
- g) The barcode stickers should be printed. One will be printed for each individual on the Cross-sectional Survey Participant Sample List. The barcode stickers will contain with the 9-digit participant ID on. Each field officer should take the barcode stickers for the individuals they will be visiting that day.
- h) Field officers should ensure they have the latest version of the SurveyCTO Baseline cross-sectional Survey Form on their smartphone, and that the smartphone is fully charged.

### **6.2. Locating and approaching the household**

- a. The field officers locate the intended household using the *Cross-sectional Survey Participant Sample List*. For each sampled participant, information collected at the census will be provided (Admin levels including village, Household ID, Household Head Name, Household Address/Information, Household Phone Number, Sampled Individual Name(s), Sampled Individual age, Sampled Individual sex, Sampled Individual ID).
- b. Open the SurveyCTO Baseline Cross-sectional Survey Form. Proceed through the form selecting the block you are in, followed by the correct field officer name. When it asks you to "*select the type of visit*" there are two options: Consent and questionnaire OR Sample collection only. Select [Consent and questionnaire].

## DeWorm3 SOP | Standard Operating Procedure 403

Title: Administering the baseline cross-sectional survey

- c. Use the information on the Cross-sectional Survey Participant Sample List to select the household you are visiting. Enter the correct administration levels (for example, PHC, HSC, Village) for the household you are visiting (take this information for the household from the Cross-sectional Survey Participant Sample List) and finally select the appropriate household ID. The household ID will be displayed alongside the household head name (hoh\_name). Double check this against the Cross-sectional Survey Participant Sample List.
- d. The smartphone will display further information for the household, such as address or locator information and telephone number of the household. Use this to locate the household. Call the household phone number for directions if you cannot locate the household. Then select [Yes].
- e. The following screen will say “*Were you able to locate the household?*” If you were, select [Yes].
- f. If it is not possible to locate the household using the information, select [No] for were you able to locate the household. Save and finalise the form and report this to the field supervisor.
- g. If, when you arrive at the house, the entire household has moved away from the area, select [No] for were you able to locate the household.
- h. On approaching the intended household, the screen will show “Try to speak with [hoh\_name] who was the first listed person in the household (provided consent)”. Ask whether the person who provided consent in the census is available (they will be listed by name on the screen). This person will hopefully answer a few additional household-level questions during the survey. It is not critical for the completion of the survey that they are present though.
- i. When asked “What sample are you collecting today?” Select [Cross-sectional]. You will not be able to select the [Longitudinal Monitoring] at this stage.
- j. The next screen will display the name(s) sex and age of the individual selected to be surveyed in the Cross-sectional Survey. Select the name you are currently looking for. You will use one form submission per individual. Then confirm whether this person is present.
- k. If not present, select [No, participant unavailable] and then you will be asked how many times you have visited this person, and then arrange a time to call back. The same option will be selected if the entire household is not available. You will be told on the next screen “Nobody is home, you have 2 more times to contact this person. Make a note to come back to the household on another occasion. Save and finalise the form now.”
- l. If the participant lives outside of the cluster during the week and returns at weekends and claims the household as their residence, they should be enrolled. Come back to enroll them when the participant is at home.
- m. If you select [No, deceased], [No, individual absent for survey period], [No, individual not eligible] or [No, permanently moved away] the form will end, Save and finalise the form now.”
- n. Ask if the household’s DeWorm3 Study Card is available, and indicate [Yes] on the phone. If it is, ask to see this and scan the barcode on the card. If not, select [No] and indicate why the card is not available.
- o. If the card is not available, select the method of entry for the Household ID you will use. The preferred option is scanning the Household’s copy of the consent form, then the extra sticker in the census log you have taken to the field, and the

last option is entering the ID manually from the participant sample list you have taken to the field.

- p. The next screen covers the consent process.
- q. It is possible to save the form and exit at any point (without finalizing). Then you can go into saved forms and reopen the form to finish it. For example, if the selected participant is not currently available but nearby and on their way over or if they are unable to provide consent because their guardian is nearby save the form and reopen it within an hour or two. If you won't be able to complete the form before the end of the day, save, finalise and submit the form.

### **6.3. Assessing the eligibility of the selected individuals**

#### **6.3.1. Household membership**

- a. When a selected individual is located and confirmed as present, field teams will verify that he / she is a member of the household. A member of the household is someone who considers it their primary residence or who is affected by the decisions of the head of the household and shares a cooking pot.
- b. If the individual is not (or no longer) a member of the household, he / she is not eligible for enrollment. Complete the survey in the tablet to reflect this.

#### **6.3.2. Migration**

- a. If the individual has moved out of the cluster permanently they cannot be surveyed.

#### **6.3.3. Provision of informed consent**

- a. Written informed consent will be required from individuals aged 18 years or greater. Parental/guardian consent will be required for any individuals under 18 years. If the child is aged 7-18 years written assent will be required from them in addition to the parental/guardian consent.
- b. If assent/consent is refused, the individual is not eligible and will need to be replaced.

#### **6.3.4. Demographics**

- a. If the individual's **name or sex is incorrect** but it has confirmed this is the same individual as in the household, correct the record in the smartphone and proceed with the survey.

### **6.4. Consent Procedures**

- a. If the potential participant is 18 years or above, only they are required to be present at the house to consent and be enrolled in the cross-sectional survey.
- b. If the potential participant is below 18 years a caregiver must be present to participate during the entirety of the consenting/assenting process.
- c. For participants aged younger than 7 years, the caregiver must provide informed consent for their participation. For participants aged from 7 up to 18 years the child must provide informed assent in addition to parental/caregiver consent. If the child is aged 7-18 years written assent will be required from them in addition to the parental/guardian consent.
- d. First determine which language the individual or their caregiver prefers and whether the individual/caregiver can read and write.

- e. Verbally explain to the potential participant and/or their caregiver the purpose of the study in general, study requirements, and the risks and benefits of study participation. This is just a single timepoint survey.
- f. Participants/caregivers will be told that participation in the Cross-sectional survey is completely voluntary and if they do not feel comfortable, they need not participate. If the potential participant or their caregiver is interested in participating in the Cross-sectional Survey and is able to read, give him/her a Cross-sectional Survey Consent Form in their preferred language to review.
- g. Read the Consent Form to the participant/caregiver and answer any questions that the participant/caregiver has regarding the study or study participation.
- h. If the participant/caregiver agrees to participate, she/he will be invited to sign the Consent Form.
- i. If the potential participant is less than 18 years of age, a caregiver must be present and participate during the entirety of the consenting/assenting process for the participant to be enrolled in the Cross-sectional Survey
- j. If the participant is a child 7 to 18 years of age, read the Assent Form to the participant. After reading the form, answer any questions that the child has.
- k. If the child agrees to be in the cohort, he/she will be invited to sign the Assent Form.
- l. After consent/assent is provided, sign the Consent and Assent Forms. Ensure that the parent/caregiver has already signed an informed consent form for the child to participate. For children aged 7-18 years both Consent Forms and Assent Forms must be signed for the participant to participate in the Cross-sectional survey.
- m. If the participant has a significant intellectual disability or is deaf/dumb they take on the same status as a child. If they are able to assent please document this as well as consent from the primary caregiver and if unable to assent, collect consent from the primary caregiver. This applies whether the participant is a child or an adult. The primary caregiver will answer the questions on the participant's behalf. Document such a case in the notes section at the end of the survey.
- n. If the participant and/or caregiver is unable to sign the Consent or Assent Forms, 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 a literate adult (aged 18 years or above) of the participant/caregiver's choice (not study staff) who has sat through the consenting process, can read the information provided and sign their own name.
- o. Provide two copies of the Consent and Assent Forms for the participant/caregiver to sign. The participant will be offered one copy and the other copy will be kept and placed in the binder for filing in the office
- p. If the potential participant/caregiver is reluctant to sign the Consent Form, then ask her/him if she/he has questions that need to be clarified.
- q. If the potential participant still indicates unwillingness to participate in the study, then thank her/him for their time and assure him/her that this will not affect their access to MDA in the future.
- r. **If the participant and/or the caregiver of the participant (if required) is *not present*** at the house to consent and to participate in the Cross-sectional Survey select [No, unable to answer at this time] in the Cross-sectional Baseline Survey Form. Save and finalise the form now. Schedule a time to return when the

participant (and or their guardian) will be home. Mark on the Cross-sectional Survey Participant Sample List that the household has been visited for the first time and a repeat visit is required.

- s. **If the participant and/or the caregiver of the participant (if required) *refuses consent***. Save and finalise the Cross-sectional Baseline Survey Form now
- t. **If the participant and/or the caregiver of the participant (if required) is *present*** select [Yes, consented] and continue with the survey

### 6.5. Household Questions

- a. After the participant consents, a few household-level questions will be asked. These should preferably be asked to the household member who answered the questions during the census – select the name of the individual who answered the questions last time round.
- b. The next question asks if that individual is present and able to speak with you. If they are, conduct the household questions with him/her. However, if that individual is not available, the questions can be answered by the participant who will provide the stool sample or their guardian.
- c. The screen displays the answer given to the question on main source of drinking water in the census and you then ask some follow up questions on whether the household does anything to the water to make it safe. If they say yes, it will ask what they do. If they say they purchase bottled water they will be asked how much money each month they spend on bottled water.
- d. Ask to **observe** how drinking water is stored in the household. If permitted, record the method of storage and observe whether stored drinking water is currently available.
- e. Ask to see where household members most often wash their hands. Record the type of handwashing facility available. Observe whether water is available, and whether soap, detergent or other cleansing material is available.
- f. Once you have finished these questions, click to indicate you have completed the household questionnaire and you will now move to the participant questionnaire.
- g. Once this household questionnaire module has been completed and the form is finalized, if you go back in future to sample another participant for the cross sectional or longitudinal survey in this household, these questions will not appear as they have been answered already.

### 6.6. Participant Questions

- a. The key information of the participant will be shown on the screen and you will be asked whether any information needs correcting. If all information is correct, select [None]. If age, sex and /or name spelling is wrong in the survey form, select these and the next screens will ask you to provide a correction.
- b. Next a set of questions will be asked to the participant (or the guardian) if the participant is a young child (under 5 years).
- c. Indicate whether the participant has swallowed medicine for worms in the last year. If the answer is yes, also ask where they got the medication.
- d. Observe and fill in the type of shoes the participant is wearing at the time the survey is conducted.
- e. Ask the participant where they usually go to defecate when at home, then ask whether they used a toilet facility last time they had to defecate at home. If the answer is no,

ask why the participant to give you the main reason why they did not use a toilet facility and select an option or specify another reason.

- f. Repeat the questions above for when the participant is out and about, for example, at work.
- g. Then ask the participant where they were when they last drank water and select the appropriate option.
- h. If the participant reported usually using a toilet facility at home, the survey will request to observe the facility. Select [observation possible/permitted] if you can observe it, and [observation not possible/permitted] if not. **These must be observations made by you, not reported by the participant/household.**
- i. Record the location of the toilet, and how long it takes you and the participant to walk there if not in the dwelling or in their yard/plot.
- j. Then observe and record the type of toilet.
  - i. **Pit latrine with open pit/only branches** – A latrine without a squatting slab, platform or seat. An open pit is a rudimentary hole in the ground where excreta is collected. It may have bare branches over it to stand on.
  - ii. **Pit latrine with slab (cement or concrete)** – A pit latrine where the pit is **fully covered** by a concrete or cement slab fitted with either a squatting hole or seat.
  - iii. **Pit latrine with traditional platform** – A pit latrine where the pit is **fully covered** by a solid platform built of local materials such as logs plastered with mud.
  - iv. **Ventilated improved pit latrine (VIP)** – A dry pit latrine ventilated by a pipe extending above the latrine roof. **Floor can be a slab or a traditional platform.** The open end of the vent pipe is covered with gauze mesh or fly-proof netting. *If the vent pipe is not covered by a gauze mesh or fly-proof netting, the facility should be classified as a pit latrine with slab or traditional platform not a VIP latrine. The inside of the VIP latrine is kept dark. If the door of the VIP superstructure is missing so that it is no longer dark inside the latrine, the facility should be classified as a pit latrine with slab or traditional platform, not a VIP latrine.*
  - v. **Water-borne: Flush or pour-flush toilet** – A flush toilet uses a tank (cistern) for flushing water and has a water seal, which is a U-shaped pipe, below the seat or squatting pan that prevents the passage of flies and odors. A pour flush toilet uses a water seal, but unlike a flush toilet, a pour flush toilet uses water poured by hand for flushing (no cistern used).
- k. If you select [Water-borne toilet], ask or observe to where the toilet flushes:
  - i. **Piped sewer system** - A system of sewer pipes (also called sewerage) that is designed to collect human excreta (feces and urine) and wastewater and remove them from the household environment.
  - ii. **Septic tank** - An excreta collection device consisting of a water-tight settling tank normally located underground, away from the house or toilet.
  - iii. **Flush to pit latrine** - A system that flushes excreta to a hole in the ground.
  - iv. **Flush to somewhere else** - A system in which the excreta is deposited in or nearby the household environment in a location other than a sewer, septic tank, or pit, (for example, excreta may be flushed to the street, yard/plot, drainage ditch or other location.)
  - v. **Flush, don't know**

- l. If it is a pit latrine, observe whether there is visible faeces round the edge. You will be able to quickly observe from the doorway of the toilet facility whether the pit opening or toilet/squatting pan have visible faeces or staining around the edge.
- m. If it is a pit latrine, use the torch on the phone to look inside and observe whether there is visible faeces in the bottom of the pit.
- n. Observe and record the material of the slab/floor of the toilet facility (Enter the predominant material observed), and the type of anal cleansing materials available, if any. Materials can be unused or used and discarded in the toilet facility or pit.
- o. Step inside and observe whether the toilet facility has a door that closes and locks from the outside. Then observe the type of walls and roof of the toilet facility. Next record whether there is a well-worn path leading from the house to the toilet facility.
- p. Finally observe whether there are facilities for washing hands within 10m of the toilet facility. If these are the same handwashing facilities observed previously (if still in or near the main household, then record [Same as previously observed].
- q. The next module of the Baseline Cross-sectional Survey Form relates to the stool sample collection.

### **6.7. Stool sample collection**

- a. Participants who have signed the consent forms and answered the questionnaire, will be asked to provide a stool sample to be sent to the lab for storage for subsequent testing via qPCR.
- b. Introduce the Stool Collection Kit materials to the participant (newspaper, toilet paper, stool container, wooden sticks, small opaque bag). Explain the contents of the Stool Collection Kit:
  - i. Newspaper will be used to “receive” or “collect” the stool
  - ii. The wooden spatula is used to transfer a portion of the stool to the container
  - iii. The tissue roll is for wiping themselves
  - iv. The container will be used to carry the stool sample back to the laboratory
  - v. The bag is to protect their privacy
- c. Apply the appropriate barcode sticker with the word “stool” to the lid of the container **before you give the pot to the participant. This barcode must match the participant ID on the Cross-sectional Survey Participant Sample List.**
  - i. If the participant cannot deposit the sample now and the container is to be left for a call-back visit later in the day or the following morning, the barcode must be placed on the container prior to giving it to the participant.
- d. Do not stick the barcode to the side of the stool container, as this is a curved surface and cannot be scanned. Do not stick it to the base of the pot, as if this is put down on a muddy/wet surface the barcode will be soiled.
- e. Write the participant’s name on the side of the stool container in permanent marker.
- f. If more than one individual has been sampled for the Cross-sectional Survey within the household, two pots may have to be left for collection the following day. To prevent the wrong lid (with the barcode) being placed on the wrong stool container, use coloured stickers (or coloured marker pens) to stick on the lid and base of the container, so that the participants know to put the lid with the red dot on the container with the red dot and the lid with the green dot on the container with the green dot.

- g. When collecting the stool containers ensure that the coloured dots on the top and bottom of the containers are matching.
- h. Give the participant the following instructions:
  - i. Ask the participant to go to the place where they usually defecate, preferably a toilet facility. If not, wherever they would usually go.
  - ii. Ask them to place the newspaper on the floor of the toilet area or ground, and deposit the stool on the newspaper.
  - iii. Using the wooden spatula they should collect enough stool to fill 2/3 of the container (you can mark a line on the container to indicate the amount required). Then they put the lid on tightly.
  - iv. Inform them to use the tissue roll for wiping themselves
  - v. Once the collection is complete they should dispose of the newspaper, wooden stick and tissue roll in the latrine facility if available.
  - vi. The collected stool in the container should be placed back into the bag and handed to you.
- i. A glove can be worn when receiving the stool from the participant, although there should be no direct contact with the stool as it will be in a container within a bag. Fresh stool is warm and the container may be slightly moist. It is important to try and keep the barcode clean and not soiled with stool.
- j. When the participant hands over the stool container, discretely check the sample (without removing the lid). Note down any comments in the SurveyCTO Cross-sectional Baseline Survey Form
- k. Scan the ID on the stool container into the Form. If the ID is soiled and cannot be scanned, enter the ID manually.
- l. If the ID does not match the ID of the participant logged in the survey, this will be flagged and you will not be able to proceed.
- m. Once collected from the participant and logged, place the stool container in the cooler box ready to transport to the laboratory. Save and finalise the form.
- n. If the participant is ready and able to give the stool sample at that stage, the stool sample should be collected the same day. Participants unable to provide a stool sample will be left with the stool containers and asked to provide a fresh morning stool the next day, following the stool collection directions provided.
- o. Arrange a time and location for the collection of the stool containers (ideally around 9-10 am the following morning. The filled stool containers should ideally be kept in the house until pick up. However, an outside location is also acceptable if the containers are above the ground in a shaded and accessible place)
- p. If the sample is to be collected the next day, the participant **must deposit the stool when they defecate in the morning**. It must not be deposited the previous evening.
- q. Insist the stool must be fresh, not from another day (for those who do not have toilets and can identify a previously deposited stool). Also emphasize the importance of the stool being collected being from the same individual who was sampled and answered the questions.

### **6.8. Returning to collect a stool sample later**

- a. If you have returned to collect a sample at a call-back visit, open a new form. Select the block you are in, followed by the correct field officer name. When it asks you to “*select the type of visit*” select [Sample collection only].

- b. Use the information on the Cross-sectional Survey Participant Sample List to select the individual you are visiting. Enter the correct administration levels ( for example PHC, HSC, Village).
- c. Indicate that you are collecting a sample for the [Cross-sectional].
- d. The form will then display the names of all the individuals in that village for whom you have obtained consent, completed the survey, and left a stool container. If you have not yet completed the “Consent and questionnaire” survey form from anyone in the village for the Cross-sectional Survey, you will not be able to proceed as no names will appear.
- e. Select the individual you are collecting the stool pot from in that village. Then once you have selected this, the rest of the household and locator information will appear to help you locate the household and confirm your selection.
- f. When you are handed the pot to scan, report anything problematic with the sample, if noticed, otherwise click “No comment”.
- g. Then scan the barcode on the top of the container. **Only if it is spoiled**, enter the code manually (A monitoring form will record how many times the barcode is manually entered versus scanned). Enter the related information for the sample.
- h. If the sample ID scanned or entered is not the same as the ID of the participant you selected this will be flagged and you will not be able to finalise the form.
- i. If the barcode and participant ID match, you will be asked to confirm with the household members that the individual listed actually provided the stool sample. Additionally enter the approximate time that the stool was deposited. Then save and finalise the form.
- j. Make arrangements for the samples to be delivered to the lab within 8 hours of being deposited by the participant.
- k. In the event that the participant is not present at this return visit, or has been unable to provide a stool sample the following day, another call-back will be planned. Ask the participant or his/her family when the most appropriate time for collection would be. Conduct a minimum of three call back attempts (on three separate days) for stool collection in the Cross-sectional Survey.
- l. Any participant unable to produce a stool sample during the three attempts should be excluded from the survey. They will later be replaced by an individual from the Cross-sectional Replacement Sampling List (Stage 2).

### **6.9. Survey completion**

- a. Save and finalise the SurveyCTO form.
- b. Prior to leaving the household, tell participants that in intervention clusters all individuals will be treated during community-wide MDA, whereas in control clusters, pre-SAC and SAC will be treated in schools.
- c. Ask the participants if they have any further questions and thank them for their participation.

### **6.10. Replacing Cross-sectional Survey participants**

- a. All participants must be visited three times, before they can be replaced in the survey.
- b. The list of reserve/replacement (stage 2) participants will not be released until all the

## DeWorm3 SOP | Standard Operating Procedure 403

Title: Administering the baseline cross-sectional survey

initial 500 participants have been visited and surveys have been logged for them. The Stage 2 list will have 100 reserve individuals on it.

- c. When the reserve/replacement list is required, this will be released for all clusters simultaneously. The list will be appended to the survey in the phone and a printed list of the individuals will be provided. The individuals will then show up listed in the village, but you will require a pin code to proceed with these individuals in the survey. The pin codes will be provided to the coordination team at the same time as the cross-sectional replacement list names.
- d. The replacement list will not be stratified by age group or sex, but where possible try to replace individuals from the original list with individuals of approximately the same agegroup and sex. This will avoid an age or sex bias in the final sample.
- d. If a further (stage 3) reserve list is required, this can be requested. This Stage 3 list will have another 100 names on it. These should only be accessed once all the Stage 2 individuals have been visited three times. This Replacement List will also be covered by a pincode for each cluster which the site coordination team can use to control access to the names.

<b>Current Document</b>			
<b>Version No.:</b>	1		
<b>Developed by:</b>	Elodie Yard	<b>Date:</b>	19 January 2017
<b>Reviewed by:</b>	Arianna Means	<b>Date:</b>	19 January 2017
<b>Reviewed by:</b>	Katherine Halliday	<b>Date:</b>	29 November 2017
<b>Effective Date:</b>	29 November 2017		
<b>Approvals</b>			
<i>I have reviewed and approve this SOP for implementation.</i>			
<b>Principal Investigator</b>	<b>Signature</b>	<b>Date</b>	
<b>Site Principal Investigator</b>	<b>Signature</b>	<b>Date</b>	

<b>Document History</b>		
<b>Version No.</b>	<b>Effective Date</b>	<b>Author(s)</b>
1	29 November 2017	Elodie Yard, Arianna Means, Katherine Halliday

