

Standard Operating Procedures for the LAKANA trial
SOP Visit-01: Conducting the enrolment visit - main study.
 Version 3.0 (2020-10-20)

1. Purpose and overview:

This SOP¹ provides step-by-step instructions on how to conduct the enrolment visit (MDA 1) in villages participating in the LAKANA trial. This SOP refers to data collection forms (DCF) DCF01a, DCF01b, DCF01c, DCF01d, DCF01e, DCF01f, DCF02, DCF02a, DCF03, DCF04, DCF05, and DCF10a.

2. Applicability to and responsibilities of various staff members

Staff member	Responsibility
District Supervisor	- Plans date of entry in villages (makes decisions on edits to the villages MDA master plan if needed)
Field Supervisor	- Packs data collectors' rucksacks - Arranges data collection team meetings - Makes sure that data are transmitted
CSCoM Technical director (DTC)	- Agrees on MDA date with village chief - Assists Field supervisor in data collection team supervision
Data collector	- Finds the compound/households and requests permission to proceed - Operates tablet computer - Prepares study drug - Provides study drug
Relais Communautaire	- Helps data collector to identify compounds and households - Facilitates discussion with head of compounds and household members

3. Required materials

Item	Number	Specification
Field supervisor's portable power bank	1	Portable power bank to be used to charge data collectors tablet computers if needed during a visit in a village.
Data collector's backpack	1	Data collector's backpack will contain the items listed below.
Staff identification badge	1	Data collector badge with:

¹ Abbreviations: SOP = standard operating procedure, LAKANA = Large-scale Assessment of the Key health-promoting Activities of two New mass drug administration regimens with Azithromycin, DTC = Directeur Technique de Centre, CSCoM = Centre de Santé Communautaire, MDA = Mass Drug Administration, CSRef = Centre de Santé de Référence.

Item	Number	Specification
		LAKANA Logo, Data collector Photo, Last name, First name, and ID.
Pad to note any concern	1	
Pen	1	
Identification Sticker for households enumerated	2 identical stickers per household	2 identical stickers (with QR code/ID): <ul style="list-style-type: none"> • One sticker to be affixed on participant information leaflet. • Second sticker to be affixed on the data collector's paper register.
Identification Sticker for 1-11 mo. old infants in households	2 identical stickers per 1-11 mo. old child	2 identical stickers (with QR code/ID): <ul style="list-style-type: none"> • One sticker to be affixed on child health card. • Second sticker to be affixed on the data collector's paper register.
Weighing scale	1	Electronic baby hanging scale.
Commercial drinking bottled water	1	Water to be used for study drug reconstitution: Bottle of 500 ml
Study drug bottle	<i>Number required to meet the daily target</i>	Each bottle of study drug contains the same amount of dry powder, either including 1.2 g of azithromycin or respective amount of placebo powder. One bottle will be sufficient on average for 10 children.
Plastic disposable syringe	<i>Number required to meet the daily target</i>	Volume: 5ml; 0.2ml graduations
Bag for waste collection	1	
Tablet computer	1	Data collection tablet Samsung Tab A 9-inch GSM tablet, model number SM-T295. The LAKANA App (providing access to SOPs, FAQs,) will be installed. The Tangerine application will be used to conduct the data collection process. For the enrolment visit, the following questionnaires will be loaded: DCF01a, DCF01b, DCF01c, DCF01d, DCF01e, DCF01f, DCF02, DCF02a, DCF03, DCF04, DCF05, DCF10a. A folder containing contact information of LAKANA supervisors, Village

Item	Number	Specification
		information (map, contact information of the Relais Communautaire) will be available.
Personal Protective Equipment (PPE) individual kit	1	1 Kit/ LAKANA staff member (For details on the kit composition and utilization, refer to <i>SOP-Safety 01 Hygiene and PPE</i>)

4. Definitions and general instructions

4.1. Definitions

- 4.1.1.** District health officer or *Médecin Chef*: the head of the district-level Referral Health Centers (CSRef) who leads a team of doctors, nurses, midwives, hygiene technicians and social workers.
- 4.1.2.** District Supervisor: a LAKANA staff member coordinating trial activities at the district level. The district supervisor reports primarily to the study coordinator and is stationed in the district office (close to or located in the CSRef). There will be 1 supervisor for each district participating in the study (each district covers ~6 CSComs: ~ 48 villages).
- 4.1.3.** Field Supervisor: a LAKANA staff member responsible for coordinating data collection teams' activities. He is under the supervision of the District supervisor.
- 4.1.4.** DTC: the health center technical director responsible for supervising CSCom health agents and Relais in Mali's community health system.
- 4.1.5.** Data collector: a LAKANA staff member collecting data at the compound, household, and individual level.
- 4.1.6.** Relais Communautaire: a volunteer chosen by the community who serves as a bridge between professional health staff and the villagers.
- 4.1.7.** Data collection team: a group that is composed of 2 to 3 members: one to two data collectors and 1 to 2 Relais Communautaire.
- 4.1.8.** Data collection hub: a secure location where the research team will preposition drugs and other study material prior to village MDAs. Daily activities such as packing of rucksacks, meetings with data collection team and data transmission will be carried out at a hub. It is at this site that data collectors and supervisors meet before starting activities in the village and at the end of the day.
- 4.1.9.** Compound: a cluster of households grouped in a delimited area. A compound may only have one household.

- 4.1.10. Household: a group of individuals who share the same cooking pot and who acknowledge the authority of a single person as the head of the household.
- 4.1.11. Head of the household: the person of authority in the household. Permission from the head of the household is required for household participation in the trial.
- 4.1.12. Eligible infant: an infant aged between 1 and 11 months (age 29-364 days) and weighing at least 3.0 kilograms at the time of study drug provision, and for whom there is no record of allergy to macrolides.
- 4.1.13. Caregiver: a person responsible for looking after a child. The caregiver is responsible for providing consent for study drug administration to eligible infants.

4.2. General instructions (Appendix 1)

- 4.2.1. During the Covid-19 epidemic, physical distancing will be enforced: a distance of at least 1 meter (3.3 feet) will be maintained between any two individuals.
- 4.2.2. Prior to village MDAs (~1 week), the district supervisor will review and edit the individual village MDA dates if needed. He will confirm the dates to the DTC who in turn will agree with the concerned village chiefs on the planned dates of entry.
- 4.2.3. Prior to village MDAs, LAKANA data collectors will conduct a census in the village (Enumeration event) i.e. enumerate compounds and households within compounds and provide study documentation (participant information leaflet) to the households. The purpose of this enumeration is to get a broader sense about the population of the village (location, size and basic information on compounds and households) to prepare for the Enrolment (MDA 1). Refer to *Guidance on conducting the Enumeration in Appendix 2*.
 - 4.2.3.1. For some villages, the Enumeration and Enrolment (MDA 1) will occur simultaneously.
- 4.2.4. Prior to village MDAs (~1 week), field supervisors will transport drugs to data collection hubs.
 - 4.2.4.1. Trial drugs are stored centrally, at the district offices in the health districts taking part in the trial. Two pharmacists will be stationed in each district office. They will manage the drugs and choose for each village the drug to be used.
 - 4.2.4.2. For villages close to district offices, the district office itself will be the data collection hub, thus the drug will be kept on site.
- 4.2.5. The day before entry in a village, the field supervisor will choose the data collectors and pack the rucksacks at the data collection hub.
 - 4.2.5.1. For villages close to a district office, the district office itself will be the data collection hub, thus the packing will happen on site.

- 4.2.6.** The field supervisor will make sure when packing the rucksacks that the right drug (i.e. intended for the village to be visited) is selected.
- 4.2.7.** On the morning of the date of entry in a village, the field supervisor will distribute the rucksacks and send the data collection team to the village.
- 4.2.8.** During the Covid-19 epidemic, the LAKANA research staff will enforce special precaution measures:
- Before sending data collectors to villages, field supervisors will measure the data collectors' temperature (forehead temperature) and assess respiratory symptoms prior to them starting work. Personnel that have any symptoms related to the virus, fever (37.5°C or higher), dry cough, sore throat or respiratory issues will be referred for Covid-testing and advised to self-isolate until they have fully recovered or their covid-test is reported as negative.
 - The field supervisor will distribute Personal Protective Equipment (PPE) individual kit (including re-usable face masks and hand sanitizer) to data collectors that are symptoms-free and will send them to the villages. Details on PPE and hygiene measures during the Covid-19 epidemic are described extensively in *SOP-Safety 01 Hygiene and PPE*.
 - Regular self-monitoring: If a data collector becomes sick during the day, they will immediately notify the field supervisor, go back home and self-isolate. The field supervisor will notify the event to the LAKANA study coordinator who will communicate further measures to take.
- 4.2.9.** The field supervisor will visit the data collection team to provide technical support, when needed. When on-site visits are not possible, the field supervisor will rely on regular phone calls.
- 4.2.9.1. During the Covid-19 epidemic, in order limit the presence of LAKANA personnel in the villages to those who are strictly necessary, the field supervisor will rely on regular phone calls.
- 4.2.10.** In a village, each data collector will work in team with one or two Relais Communautaire for one week to cover one village.
- 4.2.11.** During the Covid-19 epidemic, the LAKANA data collection team will practice and enforce physical distancing: a distance of at least 1 meter (3.3 feet) will be maintained between any two individuals. The data collection team members will wear a mask at all times when in a village.
- 4.2.12.** Upon arrival in a village and only on the first day, the data collection team, will visit and greet the chief of the village.
- 4.2.13.** The data collector guided by the Relais Communautaire will start visiting compounds listed on the tablet computer.
- 4.2.13.1. If Enumeration and MDA 1 are occurring simultaneously, there are no compounds listed on the tablet computer because this is the first contact with the village. The data collector guided by the Relais will first have to register the compounds identified (DCF01a) (*refer to Guidance for conducting the Enumeration in Appendix 2*).

- 4.2.14.** For each compound identified, the team guided by the head of compound (or his deputy) will visit the households listed on the tablet computer.
- 4.2.14.1. If Enumeration and MDA 1 are occurring simultaneously, there are no households listed on the tablet computer because this is the first contact with village. The data collector guided by the Relais will first have to register the households identified (DCF01b) within the compounds (*refer to Guidance for conducting the Enumeration in Appendix 2*).
- 4.2.15.** For each household consenting to participate in the trial (Form DCF01f), the data collector will proceed with collecting data on the household composition (Form DCF01e, DCF01c, DCF01d on the tablet computer).
- 4.2.16.** For each eligible 1-11-month old infant for whom there is a caregiver consent for treatment, the data collector will prepare and administer the study drug and record treatment information (Form DCF02 on the tablet computer).
- 4.2.17.** For each treated infant, the data collector will record immunization history and exposure to other health interventions (Form DCF03 on the tablet computer).
- 4.2.18.** For each enrolled household, the data collector will collect further information related to assets (Form DCF04 on the tablet computer), and water, hygiene, and sanitation-WASH characteristics (Form DCF05 on the tablet computer).
- 4.2.19.** Upon completion of all questionnaires and provision of study drug to eligible infants in a household, the data collector will thank the head of household (or his deputy). The data collector will visit the next household located in the compound, if any, otherwise he will proceed with the next compound.
- 4.2.20.** At the end of the day, after having visited the number of households planned, the data collector will notify the field supervisor and return to the data collection hub.
- 4.2.20.1. For villages close to district offices, the district office itself will be the data collection hub where the data collectors will return.

5. Step-by-step procedures

5.1.1. Compound identification, registration and permission (Appendix 3).

- 5.1.1.1. For each compound listed on the tablet computer, the data collector will visit the compound, introduce herself / himself to the head of the compound (or his deputy), verify that s/he is in the correct compound (i.e. verify that ID on the wall/façade, Surname and First name of head of compound match the information on the tablet computer), and explain that this is a LAKANA visit.
- If Enumeration and MDA 1 are occurring simultaneously, this is the first LAKANA visit in the compound, the data collector will first register the compound (DCF01a) (*refer to Guidance for conducting the Enumeration in Appendix 2*).

5.1.2. The data collector will start visiting the households within the compound.

5.1.3. Household identification, registration and consent (Appendix 4).

5.1.3.1. Within the compound, for each household listed on the tablet computer the data collector will conduct a visit. The data collector will introduce herself / himself, verify that s/he is in the correct household (i.e. verify that the ID, Surname and First name of head of household match the information on the tablet computer).

- If Enumeration and MDA 1 are occurring simultaneously, this is the first LAKANA visit in the household. The data collector will first register the household(s) (DCF01b) within the compound (*refer to Guidance for conducting the Enumeration in Appendix 2*).
- The data collector will clearly explain the purpose of the enrolment visit to the head of household and other household members and answer any questions that may arise (*refer to FAQs*).

5.1.3.2. The data collector will seek the head of household (or his deputy) consent for participating in the LAKANA trial (DCF01f). During the Covid-19 epidemic, the consent seeking procedure will primarily happen outdoors and in a private space: the data collection team will ask the chief of the household (or his deputy) to come out of the household.

- Seek a consent to visit the household and collect trial data on a total of nine times over a period of two years.
- Record the answer given verbally in the Tablet computer (finger signature of the chief or deputy on the tablet screen).
- If the person giving consent is not able to read the participant information and consent form, ask her / him to invite an impartial witness (any other adult of her/his choice living in the compound) to verify the consent. Record the name and signature of the impartial witness in the Tablet computer.

5.1.3.3. If consent is not granted, try to clarify further the purpose of the trial, and ask again. If consent is still not granted, thank the head of household (or deputy), mark the information into the tablet computer, and leave. The household will not be visited/asked again for consent at the subsequent LAKANA visits.

5.1.3.4. If consent is obtained, mark the information into the tablet computer.

5.1.3.5. For households that cannot be consented (for example, if no residents are at home or if the head of household (or his deputy) are absent), mark the information into the tablet computer to revisit later in the day or the next day.

5.1.4. During the Covid-19 epidemic, once household consent to participate in trial is obtained, the data collection team will ask target residents to come out of the household and implement the data collection and treatment-related activities listed below (section 5.1.5 to 5.1.8) outdoors.

5.1.4.1. If the activity must be carried out indoors, the data collection team will make sure to use the most well-ventilated areas available.

5.1.4.2. As far as possible, the data collection team will ensure adequate privacy for administering trial drug/conducting interviews.

- 5.1.5.** The data collector will conduct the household census (*Refer to Appendix 5 guidance for completing household census*).
- 5.1.6.** The data collector will provide study drug to all eligible 1-11-month old infant identified during the census in the household (*Refer to SOP Proc-01*).
- 5.1.7.** The data collector will collect information on child immunization and health interventions for each treated infant (*DCF03*).
- 5.1.8.** The data collector will collect information on household assets (*DCF04*).
- 5.1.9.** The data collector will collect information on WASH (*DCF05*).
- 5.1.10.** Ending of a visit
- 5.1.10.1. The data collector will thank the household head, plan the next visit, and proceed with the next household located in the compound, if any.
- 5.1.10.2. If there are no other households located in the compound, the data collector will thank the head of compound (or his deputy) and proceed with the next compound to visit.
- 5.1.11.** Closing of the day
- 5.1.11.1. After having visited the number of households planned for the day, the data collector will thank the Relais Communautaire and return to the data collection hub.
- For villages close to district offices, the district office itself will be the data collection hub where the data collectors will return.
- 5.1.12.** The data collectors will transmit the data to the server, disinfect the material (tablet computers) as described in *SOP-Safety 01 Hygiene and PPE*, leave the material and return home. They will come back the next morning to pick the rucksack.
- 5.1.13.** The field supervisor will manage clinical waste and remaining drugs, and s/he will charge the tablet computers and store all study material.
- 5.1.14.** The field supervisor will report to the district supervisor on the study progress and on any issues that need to be addressed.

6. Occupational Safety Issues

In a non-epidemic situation, there are no specific occupational safety issues.

During COVID-19 epidemic, procedures for safe and proper work will be used to reduce the risk of exposure to a hazard and prevent transmission between the study team and the study participants. Special considerations due to COVID-19 are presented in *SOP-Safety 01 Hygiene and PPE*.

7. Quality Assurance / Quality Control

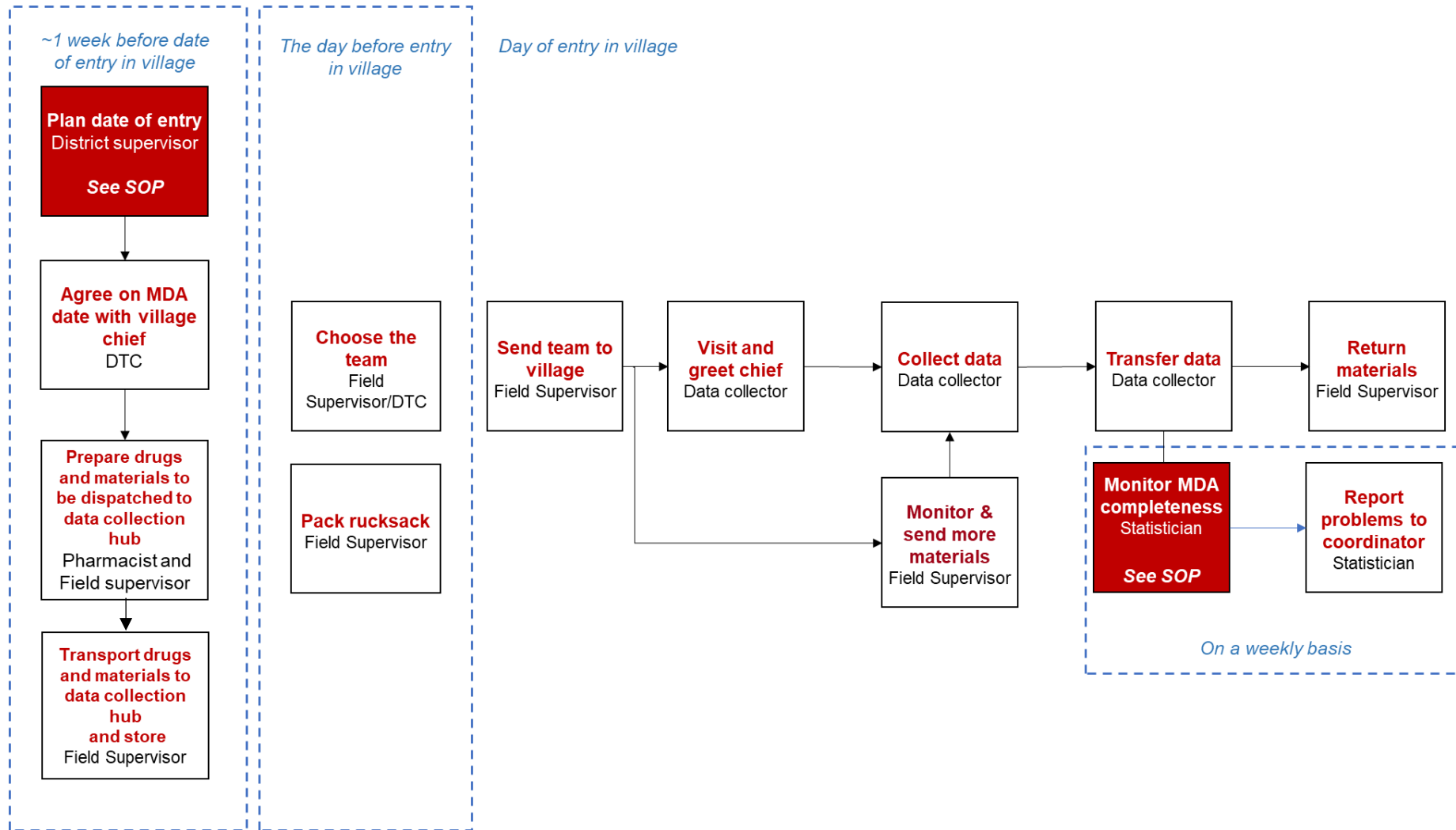
8. Appendices and other related documents

Document number	Document content
Appendix 1	Flowchart for Conducting the Enrolment Visit
Appendix 2	Guidance for conducting the Enumeration
Appendix 3	Flowchart of Compound Identification, Registration and Permission
Appendix 4	Flowchart of Household Identification, Registration and Consent
Appendix 5	Guidance for completing household census

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0 (2020-08-25)	Authored by Laura Adubra in consultation with LAKANA investigators. Approved by LAKANA PSG.
Version 2.0 (2020-10-06)	<p>Edits:</p> <ul style="list-style-type: none"> - Information and instructions to conduct the Enumeration event added (Section 4.2.3 and Appendix 2). - Clarified that the census team will give study documentation (participant information leaflet) to the household at the enumeration stage (Section 4.2.3 and Appendix 2). - 2 identical stickers per household enumerated will be issued: one sticker to be affixed on household participant information leaflet and one sticker to be affixed on data collector's paper register (section 3 Required Materials and Appendix 2). - 2 identical stickers per 1-11 mo. old child identified will be issued: one sticker to be affixed on child health card and one sticker to be affixed on data collector's paper register (section 3 Required Materials and Appendix 5). - Appendix 2 (Guidance for conducting the Enumeration) added - Appendix 5 (Guidance for completing household census) added - Appendices 3 and 4 revised to include Enumeration-related activities <p>Authored by Laura Adubra in consultation with LAKANA investigators. Approved by LAKANA PSG.</p>
Version 2.0 (2020-10-06)	<p>Edits:</p> <p>Removed drug provision from the responsibilities of the Relais. The data collector will handle both drug preparation and administration (Edits in Table 2; section 5.1.6).</p> <p>Authored by Laura Adubra in consultation with LAKANA investigators. Approved by LAKANA PSG.</p>

Appendix 1: Flowchart for Conducting the Enrolment visit



Appendix 2: Guidance for conducting the enumeration.

The enumeration event in LAKANA trial will happen prior to the enrolment event (i.e. MDA #1) in villages participating in the trial.

The enumeration is the procedure of systematically enumerating compounds and households within compounds and acquiring and recording basic information on their composition. The DCF01a and DCF01b forms will be used for the enumeration process.

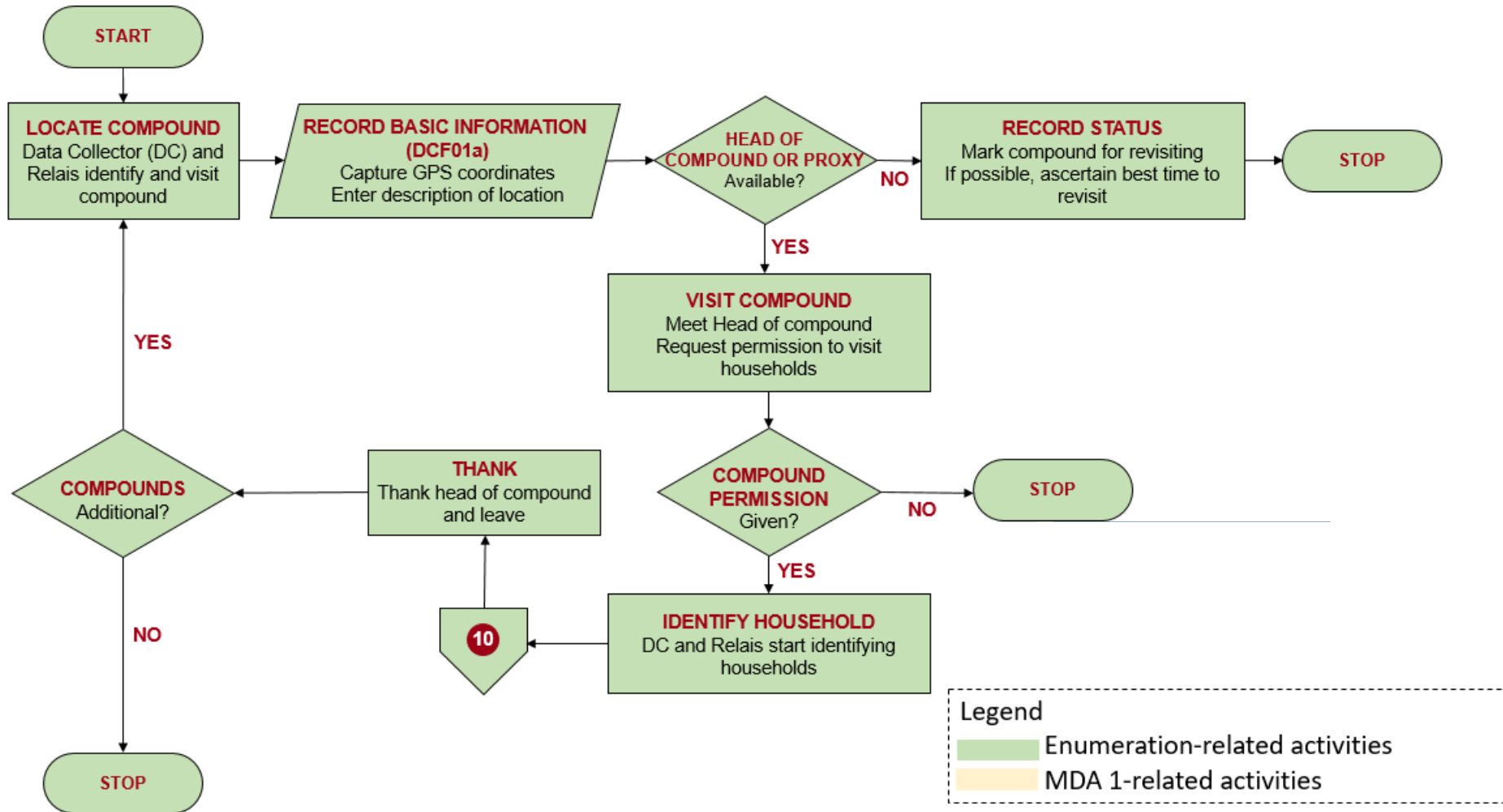
General instructions for the enumeration are listed below:

1. Upon arrival in a village, the census team members will introduce themselves to the village chief prior to starting the enumeration and explain the purpose of their visit.
2. With the help of a Relais from the village, the census agents will start identifying compounds.
3. For each compound identified, the census agent will use DCF01a (= “Add Compound”) and start recording information:
 - 3.1. An ID will be assigned to the compound by the data collection system.
 - 3.2. The census agent will ask the permission of the head of compound/deputy to place (paint or write) the ID number on an exterior façade or side or wall of the compound. *The objective of placing the identifying number is to allow the data collectors that will visit the village at MDA #1 to identify the compounds and open the right records on their tablet computers.*
 - 3.3. The census agent will complete DCF01a as guided by the software.
4. If permission is given to proceed in the compound: for each household identified within the compound, the census agent will use DCF01b (= “Add Household”) to record household information.
 - 4.1. An ID will be issued to the household and scan/enter in the tablet. The census team will affix 1 sticker having the QR code/ID on the printed documentation (participant information leaflet) and give it to the head of the household (or his deputy). The census team will affix a second sticker (identical to the first one i.e. same QR code/ID) on his paper register.
 - 4.2. The census agent will complete DCF01b as guided by the software.

NB 1: Unless both Enumeration and MDA 1 events are conducted simultaneously, there is no request of consent to participate in LAKANA trial at the enumeration. The consent process will happen at the enrolment event: MDA #1.

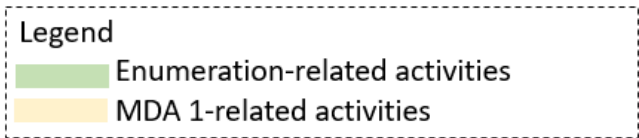
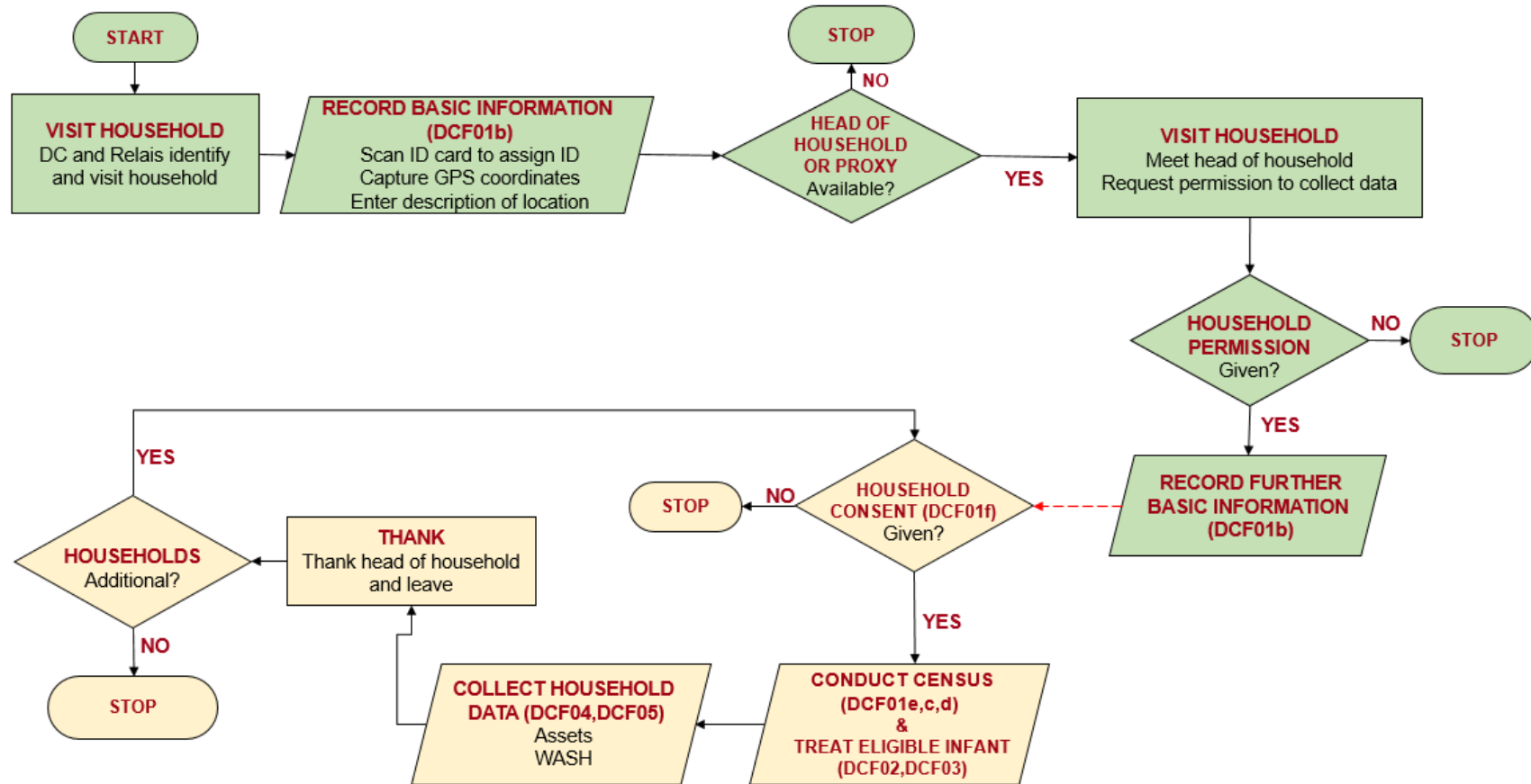
NB 2: There is a possibility that in a village, the census agents will miss some compounds or households. There will still be a possibility at MDA #1 for the data collectors to add new compounds/households in the system: Forms DCF01a and DCF01b will be available on their tablet computers to add any newly identified compounds/households.

Appendix 3: Flowchart of Compound Identification, Registration and Consent



Appendix 4: Flowchart of Household Identification, Registration and Consent

10 HOUSEHOLD IDENTIFICATION, REGISTRATION AND CONSENT



Appendix 5 - Guidance for conducting the household census.

The DCF01e, DCF01c, and DCF01d forms are to be used to collect previous mortality in the household and enumerate the members of a household within a compound. The data collection is hierarchical: first a compound is approached, and permission is requested, then for each household within the compound, consent is requested, and a primary respondent is identified. The primary respondent, often the first wife of the head of household, provides information on herself and her children. Other wives are also interviewed, and the process continues until all household members have been enumerated.

General instructions for the census are given below:

1. If household consent has been provided (DCF01f), ask the head of the household questions about previous mortality in the household (DCF01e).
2. When DCF01e is completed, ask the head of household if you can speak to his wife or, if he is not married, or she is not available, ask the head of the household to designate a proxy.
3. Create a record for the wife (or proxy) (“Add adult” button) and complete the adult form (DCF01c) as guided by the software.
4. Ask the wife to list all the children for which she is the caregiver, starting with the youngest and proceeding by increasing age until all children are listed.
 - 4.1. For each child, create a record (“Add Child” button) and complete the child form (DCF01d) as guided by the software starting by scanning the QR code/entering the ID.
 - For 1-11 months old infants, affix one sticker with the QR code/ID marked on it to the child’s health card. Affix the child second identical sticker (i.e. having the same QR code/ID marked on it) to the paper register.
 - For 1-11 months old infants, complete the other required forms.
5. In collaboration with the first wife, identify any other wives that live in the household and repeat the process (starting at §3) for each wife.
6. After all wives and children have been entered into the tablet, return to the first wife and review the list of household members. Ask her to identify any other household members.
 - Other resident children.
 - Other male and female family members.
 - Other residents, such as servants.
7. Enter the required information in the tablet for each adult.
8. For any other children, proceed as stated in §4.1.
9. Review the complete list of household members with the wife and if correct, proceed with the remainder of the visit.