FIEBRE Standard Operating Procedure F.12		
Title	**Selection, Recruitment & Enrolment of Community Controls**	
SOP Reference	***Version***	***Date of effect***
F.12	2.1.2	27 Dec 2018

SOP Development

	Name	Title	Signature	Date
Author	John Bradley	Statistician		
Author	Heidi Hopkins	Scientific Program Co-ordinator		
Reviewer	Kate Haigh	Clinical Governance Co-ordinator		
Approver				

Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
30 June 2018	Kate Haigh		22 Nov 18
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Revision History

Version No.	Effective date	Reason for change
2.0	22 Nov 2018	Updated to pharyngeal swabs (not just NP)
2.1.2	27 Dec 2018	Minor formatting updates

SOP User Confirmation

I acknowledge that I have read, understood and agree to follow this SOP

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1 Title: SELECTION & RECRUITMENT OF COMMUNITY CONTROLS

2 Purpose: To describe the procedures for identification, selection, recruitment and enrolment of community controls for the FIEBRE study.

3 Responsible staff: [adjust based on site personnel]

4 Background & Rationale: Interpreting the results of some serological assays and pharyngeal swab assays requires knowledge of background prevalence of infection or colonization in the study population. To address this, we will include 600 control participants from the community that lives in the catchment area of the health facility for each FIEBRE site. The controls will be frequency matched to selected outpatients by age, gender, place of residence, and month of enrolment (to address seasonality). To reach a total of 600 controls over the 12-month study, we will enrol about 50 controls per month.

To define the catchment area for outpatients and community controls, we will combine existing data and pilot data from each site to define an area around the study facility in which approximately 80% of outpatients live. Residing within this area is a selection criterion for FIEBRE outpatients. Community controls will be recruited within this area.

For the purposes of the FIEBRE study, “recruitment” means identifying potential participants and inviting them to consider study participation. “Screening” refers to the process of systematically applying the study selection criteria to each recruited (or invited) potential participant. “Enrolment” means formally including, or enrolling, an individual who meets all selection criteria as a study participant.

Community controls will be enrolled if they meet the screening criteria described in our protocol and in this SOP, and if they (or their parents/guardians) provide informed consent. FIEBRE study staff will obtain blood and pharyngeal samples from community controls, and will ask the controls (or their parents/guardians) about illnesses and medicine use in their household.

5 Supplies and Materials

- List of characteristics for identification of specific community controls (see item 6.1.3)
- ODK tablet or paper form, “Control participant questionnaire”
- Control screening and enrollment logbook (if using paper forms)

- Information Sheet and Consent Form for study participation – Controls (in appropriate language)
- Information Sheet and Consent Form for future use of biological specimens – Controls (in appropriate language)
- Where appropriate: Informed Assent Forms for children old enough to understand study participation – Controls
- Ink pens
- Ink pad (for fingerprints)
- Items to obtain blood and pharyngeal samples from controls (see SOP F.14)

6 Procedures:

6.1 Frequency matching of controls to randomly selected outpatients

6.1.1 The ODK data system regularly uploads FIEBRE study data, including data from outpatient participants, to the central data server (read-only accessible to both to the study team at each site, and to the LSHTM team). These data will provide the basis for selection of community controls.

6.1.2 Using a standardized analysis command in ODK, twice each calendar month the LSHTM data team will summarize key data (age, gender, place of residence) for all outpatients enrolled at each site in the previous 15 days (or since the previous summary, if it is more than 15 days ago).

6.1.3 On the same schedule, twice per calendar month, the standardized analysis command will randomly select 25 of these outpatients for frequency matching of controls. The LSHTM data team will communicate with the site team to confirm three (3) key characteristics for each of the selected 25 outpatients:

a) Location of residence,

b) gender,

c) and age, within the following age bands:

≥2 to <6 months
≥6 months to <1 year
≥1 to <3 years
≥3 to <5 years
≥5 to <10 years
≥10 to <15 years

≥15 to <20 years
≥20 to <25 years
≥25 to <35 years
≥35 to <45 years
≥45 to <55 years
≥55 to <65 years
≥65 to <75 years
≥75 years

6.2 Recruitment and enrolment of control participants

6.2.1 Controls must be recruited within 15 days of confirming the information described in item 6.1.3.

6.2.2 For each control to be recruited, go to the given location, and identify the residence nearest to the given location.

6.2.3 At the identified residence, speak to the household occupants to ask whether there is a potential control present who is a) resident in the house, b) the gender indicated, c) in the age band indicated and d) willing to give written informed consent (or has a parent/guardian present willing to consent, for children) to participate in the study.

Note: To preserve the privacy of study participants, it is important to use the exact language in the consent document when recruiting control participants. Don't tell potential controls that they have been matched to a FIEBRE study patient. Just explain that you are conducting a study on fever in their area, and that you are seeking a control with specific age, gender and residence data as selected by a computer.

6.2.4 If yes, obtain informed consent (SOP F-02), enrol the control participant, and proceed conduct the control questionnaire and take the samples (SOPs F-13, F-14).

Note: In some cases, a household occupant may meet the criteria to be a control, but not have time to complete the control activities at the time of recruitment. If this happens, make an appointment with the person as soon as possible to complete enrolment and study activities. The appointment can be at the control's home, at the study facility, or at another convenient location.

6.2.5 If there is no-one who meets control criteria in the first residence, go to the next closest residence, and repeat the procedure in 6.2.3. If someone in the second residence meets control criteria, enrol

her/him as in item 6.2.4. If not, then carry on to the next closest residence until a control is enrolled.

Note: To identify the “next closest residence,” stand facing the door of the first residence. Turn to your left and walk in a straight line; approach the very next residence that you reach. (Depending on your site’s context, this may be a house, a hut, a flat or apartment, or another household unit within the same building.) If you cannot go left – because of a wall, a field, or other large non-residential structure or space, go right. If you cannot go right, go up (e.g. upstairs). If you cannot go up, go down. If you cannot go down, go left. Proceed in this way until you identify a control that matches the age, gender and consent criteria.

7 Documentation: FIEBRE protocol (version 2.7, 15 Oct 2018) section 7.5;
see also:
SOP F-02 Informed consent/assent procedures,
SOP F-13 Completion of CRF for controls,
SOP F-14 Collection and processing of samples from controls: venous blood, pharyngeal swabs