FIEBRE Standard Operating Procedure F.01			
Title	**Patient Recruitment, Screening & Enrolment Procedure**		
SOP Reference		***Version***	***Date of effect***
F.01		2.1.1	17 Dec 2018

SOP Development

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Due date for next review	Reviewer name	Signature	Date reviewed
31 Oct 2018	Kate Haigh		20 Nov 18
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Revision History

Version No.	Effective date	Reason for change
2.0	5 Oct 2018	Amendment of selection criteria (definition of fever; respiratory symptoms in patients aged <15 years)
2.1.1	17 Dec 2018	Correction of minor typographical errors

SOP User Confirmation

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

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1 Title: PATIENT RECRUITMENT, SCREENING, & ENROLMENT PROCEDURE

2 Purpose: To describe the procedures for recruitment, screening and enrolment of inpatients and outpatients for the FIEBRE study.

3 Responsible staff: [site-specific]

4 Background & Rationale: For research studies, it is important to take a systematic approach to selecting and enrolling study participants. 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.

FIEBRE study patients will be drawn from those who come to the participating health care facilities seeking care. Patients of all ages two months and older, and who have fever, are eligible for screening. Selection criteria are as follows:

1) Axillary or tympanic temperature ≥37.5°C at presentation documented by health facility or study staff;
2) Age ≥2 months (two months or older);
3) Not having been hospitalized or having undergone surgery in the previous month;
4) For outpatients, residence (at the time of enrolment) within the defined catchment area around the health facility;
5) For outpatients aged ≥15 years, absence of symptoms of lower respiratory infection and of diarrhoeal diseases as defined by:
    a. cough AND ≥1 of the following: cough productive of green/yellow sputum, or haemoptysis;
    b. ≥3 loose stools within the previous 24 hours;
6) For outpatients aged ≥2 months to <15 years, absence of symptoms of diarrhoeal diseases as defined by:
    a. ≥3 loose stools within the previous 24 hours;

7) Willingness and ability to provide demographic and clinical information, and clinical samples, at the time of enrolment and 28 days later;

8) Provision of written informed consent for adult participants (or from next of kin if the patient lacks capacity); and for children, provision of written consent from a parent/guardian and assent from the child (according to local regulations and practices at each study site).

This SOP describes the procedure for screening potential participants according to the selection criteria listed, and for enrolling participants into the study.

5 Supplies and Materials

- ODK tablet or paper form, “Screening & Enrolment”
- Screening logbook (if using paper forms)
- Enrollment logbook (if using paper forms)
- Ink pen (if using paper forms)

6 Procedures:

6.1 Pre-screening: Identifying and referring potential study participants

6.1.1 [This will depend on set-up and personnel at each study facility. **For example:]** The health center [receptionist/clerk/nurse] is typically the first to interact with patients coming for care. Every patient who comes to the health center should be considered for possible enrollment into the study. For each newly presenting patient, the [receiving staff] should consider the following question:

- Is the patient’s axillary or tympanic temperature 37.5°C or higher?

If the answer is “YES,” the [receiving staff] should briefly tell the patient (or parent/guardian) that s/he may be eligible for a research study taking place at the health center. If the patient/parent/guardian agrees, the [receiving staff] should refer the patient to the study staff. **If the patient is very ill, referral must not delay care by health facility staff.**

6.1.2 Each site should design an appropriate method, based on study site logistics and capacity, to**:**

a) estimate the **total number of patients with fever who present to the study facility/-ies over the course of the study period;** and

b) tally the **total number of patients who are pre-screened,** i.e. who have their temperature checked as in item 6.1.1, and **who are either referred or not referred** to study staff for further screening.

6.2 Screening procedure

6.2.1 The screening procedure is conducted by study staff. Begin the screening procedure as follows:

- Introduce yourself by name to the potential participant (or parent/guardian). Briefly explain the purpose of the study, and the screening procedure.
- Complete one Screening & Enrolment Form (ODK or paper) for each patient screened.

6.2.2 For inpatients, there are six (6) selection criteria for FIEBRE, corresponding to the points in the Screening & Enrolment Form for Inpatients. For outpatients aged <15 years there are eight (8) selection criteria; and for outpatients aged ≥15 years there are nine (9) selection criteria; all corresponding to the Screening & Enrolment Form for Outpatients.

6.2.3 Consider each selection criterion in the order presented by the ODK tablet or paper form. Mark the appropriate answer – yes or no – for each criterion in the order listed. Additional details are in section 7 below. **It is important to consider each criterion in the sequence presented; e.g. do not jump to any criterion without answering all the criteria preceding it.**

6.2.4 **If using ODK**, touch the screen icons to answer each question in sequence. If an answer meets selection criteria, ODK will proceed to the next criterion. If any answer does not meet selection criteria, ODK will inform you that the individual does not fulfill criteria for enrolment; if this happens, complete and "send" the screening form. **If using the paper form,** tick the box beside each question to indicate the answer. If the answer to a question falls into the white area, the individual fulfills that selection criterion; if an answer falls into the shaded (gray) area, s/he doesn't fulfill that criterion. After completing all the screening questions, if any answer does not meet all selection criterion (i.e. if any answer falls into the shaded/gray area), tick "NO" in the space by "ENROLLED?" Write your own initials in the space by "Study staff member's initials." File the form in the folder for completed Screening & Enrolment Forms.

6.2.5 **If the person being screened does not meet all study criteria**, thank them (or parent/guardian) for their time, and tell them that they are not eligible for study participation, but are welcome to continue obtaining routine care at the health facility.

6.2.6 **If the person screened <u>does</u> meet all study criteria** (i.e. with the paper form, if the answer to all seven questions fall into the white areas), enroll them as a study participant. For the paper form, tick “YES” in the space by “ENROLLED?”

- To complete the enrollment, assign a unique study number.
- **If using ODK**, a unique identifier will be assigned by ODK.
- **If using paper forms**, use the enrollment log to assign the next sequential study number to the new participant, and write the number in the space provided in the table. Write your own initials in the space by “Study staff member’s initials.” File the form in the folder for completed Screening & Enrollment Forms.

6.3 Notes on study selection criteria

The study staff member conducting the screening is responsible for confirming that the patient does or does not meet all selection criteria for the study. In case of any uncertainty about the answers to the questions listed on the Screening & Enrolment Form, study staff should confer with health center clinical staff, with the patient’s (or parent/guardian’s) permission.

6.3.1 The patient’s body temperature (question 1) may be documented by either health facility staff or study staff, using either axillary or tympanic thermometer:

- To use the axillary thermometer: [site coordinators, please complete as appropriate for your site]
- To use the tympanic membrane thermometer: Place a new cap on the earpiece and turn on the thermometer. Gently pull the external part of the patient’s ear back and up to straighten the ear canal. Insert the thermometer into the patient’s ear and press the “Measure temperature” button. Hold the thermometer steady until it beeps. Gently remove the thermometer from the patient’s ear, and read the temperature result in digital display window. Remove the earpiece cap and either discard it with regular rubbish, [or clean it thoroughly with disinfectant for re-use.] (See also tympanic thermometer package insert.)

6.3.2 Questions 2 onward in the Screening & Enrolment Form can be answered by talking with the patient (or parent/guardian, or family

members if the patient is severely ill and unable to communicate clearly), and if necessary, with health center staff.

6.3.3 If a patient meets the first 5 criteria on the inpatient form, or the first 7 criteria on the child outpatient form, or the first 8 criteria on the adult outpatient form complete the informed consent procedure (see SOP F.02).

6.3.4 After the informed consent documents are signed, complete the enrollment as in step 6.2.4 above.

6.3.5 **Note:** It is acceptable for a person to participate in the FIEBRE study more than once. A person who previously participated as a patient may participate again (as either a patient or a control), as long as s/he is outside the 28-day follow-up period, if s/he meets all study criteria. A person who has already participated as a control may participate again as a patient or control if s/he meets all study criteria.

7 Documentation:

- FIEBRE protocol (version 3.0, 31 Oct 2018) sections 6 and 7.2, and
- Screening & Enrolment Form (protocol Appendix C dated 5 Oct 2018).
- Refer also to the **supplemental "Diagram" for SOP F.01**,
- and to SOP F.02 for item 6.3.4, obtaining informed consent.