

FIEBRE Standard Operating Procedure F.09		
<b>Title</b>	<b>Scheduling a patient's study follow up and storage of contact information</b>	
<b>SOP Reference</b>	<b>Version</b>	<b>Date of effect</b>
F.09	1.1.2	18 Dec 2018

### SOP Development

	<b>Name</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>
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<b>Approver</b>				

### Review Tracker

<b>Due date for next review</b>	<b>Reviewer name</b>	<b>Signature</b>	<b>Date reviewed</b>
31 July 2018	Kate Haigh		21 Nov 18
20 Dec 2018	Kate Haigh		18 Dec 18
12 Feb 2018			

### Revision History

<b>Version No.</b>	<b>Effective date</b>	<b>Reason for change</b>
1.1.2	18 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: Scheduling a patient's study follow up visit and storage of contact information**

**2 Purpose:** To describe the steps that are going to be taken to schedule a follow up visit and how contact information of participants is going to be kept

**3 Responsible staff:** [Site-specific, adjust according to site personnel]

**4 Background & Rationale:** Completion of tasks on all non-control participants will require a twenty eight day follow up. To address loss of participants to follow up there is need to have a proper schedule for the patient and storage procedure of the patient's contact information for easy tracing of the participants. To address this we will need to take every participants' contact details which includes; place of residence, phone number, next of kin phone number, physical address and important landmarks that are closer to their home. A minimum of 3 documented contacts (usually 2 phone calls and a home visit) must be made on separate days usually on available contact numbers.

We must also store all participants' contact information so that, in the event of a positive result (e.g. blood culture, or brucellosis months down the line), we can contact the participant to provide treatment where necessary.

**5 Materials and supplies:**

- Patient study card
- Ink pen
- Locator form
- Lockable cabinet
- ODK tablet

**6 Procedures:**

**6.1 Scheduling the participant for their next visit**

- 6.1.1 Scheduling a study follow up and storage of contact information must be done on every Day 0 FIEBRE participant
- 6.1.2 The clinical staff are the ones to schedule and obtain contact information for all participants
- 6.1.3 At the end of eCRF in the tablet, the ODK system automatically provides the next date of appointment

depending on the day the participant is enrolled into the study.

- 6.1.4 Use the patient study card to record the date shown in the tablet. Using the ink pen record the date of enrolment, the day of next appointment and patient study ID number.
- 6.1.5 Sketch the map on the locator form. Record the participant's phone number (if they have a telephone) and the details of next of kin to be used during the time of tracing if the participant does not show up on scheduled date or need to be located to advise of a positive test result

## **6.2 *Assessing participants understanding of the appointment date***

- 6.2.1 Before the participant leaves the study room show him/her or parent/guardian as appropriate the next appointment date on the patient study card.
- 6.2.2 Make sure the participant understands what is written on the patient study card. Ask the participant if it is okay to call on the given phone number (if applicable) or to visit using the sketch map provided.

## **6.3 *Keeping the files with the patient identifier***

- 6.3.1 Lock the locator form in the lockable filing cabinet to ensure the confidentiality of the participant's information as per the informed consent process

## **7 Documentation:**

FIEBRE protocol (version 2.6, 20 Aug 2018)

SOP F-02 informed consent/assent procedures

SOP F-03a Completion of clinical CRF for child patients (aged <15 years) on Day 0

SOP F-03b Completion of clinical CRF for adult patients (aged ≥15 years) on Day 0

SOP F-13 Completion of CRF for controls