FIEBRE Standard Operating Procedure F.03b			
Title	**Completion of clinical CRF for adult patients (aged ≥15 years) on Day 0**		
SOP Reference		***Version***	***Date of effect***
F.03b		1.1.2	17 Dec 2018

SOP Development

	Name	Title	Signature	Date
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
31 July 2018	Kate Haigh		20 Nov 18
18 Dec 2018	Kate Haigh		17 Dec 18

Revision History

Version No.	Effective date	Reason for change
1.1.2	17 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: Completion of clinical CRF for adult patients (aged ≥15 years) on Day 0

2 Purpose: To describe the procedures for completing the above CRF

3 Responsible staff: [site-specific]

4 Background & Rationale:

The rationale for using CRFs in a study is to ensure that the data is collected in a way that minimizes inter-observer bias and data collection errors. It is also necessary to ensure that the data collected is complete and traceable to the health care worker collecting the data and the patient who has consented to supply it. The CRFs will collect all the patient data that has been set out in the protocol.

The data recorded within the CRF is used directly as the basis for the trial report, and any publications resulting from it. It is of fundamental importance to the study that it is filled in correctly and conscientiously

5 Supplies and Materials

- Data collection tablet loaded with ODK data capture forms
- Pen

6 Procedures:

6.1 The ODK data capture system contains prompts at each data entry page which are an integral part of this SOP. It is important to work methodically through the CRF and to use the prompts to guide you. This SOP should therefore be used in conjunction with the hints and prompts in the ODK system

6.2 If a particular piece of information is not available you may skip a page and go back to it later

6.3 You may save a partially completed form by clicking to floppy disk icon if you are waiting for further information (for example drug history) and go back to the form later

6.4 All forms should be fully completed by the end of the day and uploaded to the server regardless of their completeness

6.5 Every effort should be made to complete each form in full, however if a piece of information is not available the question should be appropriately marked and the reason for the information not being available recorded

6.6 The CRF questions should not be read out verbatim to participants. The collection of data should follow a conversation with the participant (and/or guardian) about their illness, followed by the clinician or field worker completing the form, in the same way that a normal medical history is taken from a patient. However do complete the form by working through it in sections to ensure the data collected is compete and avoid unnecessary toing and froing through the document

6.7 One form should never be started by one clinician and finished by another, however it is perfectly acceptable to confer and to seek advice if it is ever unclear what a response should be

7 Documentation: FIEBRE protocol (version 2.5, 31 Jul 2018), ODK clinical CRF for adult patients