FIEBRE Standard Operating Procedure F.06b		
Title	**HIV Testing and Results Recording**	
SOP Reference	***Version***	***Date of effect***
F.06b	1.1.2	18 Dec 2018

SOP Development

	Name	Title	Signature	Date
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Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
01 Dec 2018	Kate Haigh		20 Nov 18
03 Jan 2019	Kate Haigh		18 Dec 18
12 Feb 2019			

Revision History

Version No.	Effective date	Reason for change
1.1.2	18 Dec 2018	Minor formatting corrections

SOP User Confirmation

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

#	Name (print)	Signature	Date
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1 Title: HIV TESTING AND RESULTS RECORDING

2 Purpose: To describe the procedures for testing and recording results of HIV tests for participants in the FIEBRE study.

3 Responsible staff: FIEBRE laboratory staff [adjust based on site personnel]

4 Background & Rationale: One of FIEBRE's specific primary objectives is "to determine how fever aetiology varies according to patient age, geographical area, local malaria and HIV prevalence, and other risk factors." In order to address this objective, we will perform HIV testing for study participants whose status is not already documented at FIEBRE study sites where HIV prevalence is known to be >1% in the general adult population (Malawi, Mozambique, and Zimbabwe).

Malawi, Mozambique and Zimbabwe have well-established national guidelines and programs for HIV testing. **HIV testing of FIEBRE study participants should follow local guidance and standards; site-specific SOPs should be developed and followed.** This SOP provides some general principles for HIV testing and data use in the FIEBRE study, and may be used in conjunction with local SOPs, test kit manufacturer's package inserts, and/or local job aids (pictorial instruction sheets).

5 Supplies and Materials

- Sample logbook (paper or ODK)
- HIV testing results form (paper or ODK)
- HIV rapid test kit/s (per site guidelines and standards)
- Participant's whole blood sample in EDTA tube
- Sample labels with patient's QR code
- Gloves (single-use latex or vinyl)
- Tube rack
- Calibrated pipette and pipette tips, or blood transfer device provided in HIV test kit/s
- Sharps bin
- Biohazard disposal system

6 Procedures:

6.1 Preparing and reading HIV rapid tests

6.1.1 Only prepare HIV tests for FIEBRE participants – patients and controls – who are not known to be HIV-positive. If a participant has documentation of HIV infection, there is no need to repeat the test.

6.1.2 Ensure all local guidance and standards for pre-test counselling have been met.

6.1.3 Wear latex or vinyl gloves when handling blood and blood-contaminated materials.

6.1.4 Use the participant's blood from the EDTA tube to prepare HIV rapid test/s.

6.1.5 Prepare and read HIV rapid test/s according to local guidance and SOPs.

6.2 Recording and reporting the HIV test result/s

6.2.1 Record the HIV test result/s in the patient's ODK record or paper logbook.

6.2.2 Report the result as soon as possible to the clinical team managing the study participant.

6.2.3 If a study participant is ≥18 months and has a positive HIV antibody test, the positive result will be recorded in study data; for FIEBRE study purposes, there is no need for further testing.

6.2.4 If a positive HIV result is obtained in a participant <18 months, perform confirmatory testing according to local standards and guidelines.

6.2.5 **Ensure all local guidance and standards for post-test counselling – including linkage to care for those testing HIV-positive – are met.**

7 Documentation:

FIEBRE protocol (version 2.6, 20 Aug 2018) sections 7.3, 7.5, and 7.6.3; and site-specific SOPs