FIEBRE Standard Operating Procedure F.16			
Title	**Identifying and Reporting Serious Adverse Events (SAEs)**		
SOP Reference		***Version***	***Date of effect***
F.16		1.1.2	27 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
20 Dec 18	Kate Haigh		27 Dec 18
12 Feb 19			

Revision History

Version No.	Effective date	Reason for change
1.1.2	27 Dec 2018	Minor formatting updates

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: IDENTIFYING AND REPORTING SERIOUS ADVERSE EVENTS (SAEs)

2 Purpose: To describe the procedures for identifying and reporting SAEs during the FIEBRE study.

3 Responsible staff: [site-specific]

4 Background & Rationale: When we perform research with human participants, regulatory and ethical standards require that we identify and report "adverse events" among study participants. An adverse event is defined as any "untoward medical occurrence" (bad or negative clinical outcome) in a study participant. A **serious adverse event (SAE)** is any untoward medical occurrence that:

- results in death;
- is life-threatening;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity;
- consists of a congenital anomaly or birth defect.

Other "important medical events" may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

The Research Governance and Integrity Office (RGIO) of the FIEBRE study sponsor, the London School of Hygiene and Tropical Medicine (LSHTM), has requested reports of SAEs (not all AEs) that occur in FIEBRE participants. **SAE reporting guidance from the LSHTM RGIO is described in this SOP, and in section 8 of the central study protocol.** The guidance considers the fact that FIEBRE is an observational (not interventional) study. In addition, many participants enrolled in the FIEBRE study will be inpatients, and therefore already potentially seriously ill and at risk of SAEs. Our goal is to accurately identify and report any SAEs that do occur among study participants.

Many research sites and national authorities have independently established requirements for SAE reporting. **It is the responsibility of each study site co-ordinator and team to be aware of, and to follow, any reporting requirements that are relevant for your site.**

5 Supplies and Materials

- SAE report form – use your site's template if appropriate, or the template provided as an Appendix to this SOP
- Ink pen

6 Procedures:

6.1 Identification of SAEs

6.1.1 SAEs are normally identified by clinical staff or study staff in the course of usual study activities (such as interviewing and examining study participants, following up study participants, recording clinical data, and other interactions).

6.1.2 In the FIEBRE study, SAEs including any of the following in a study participant:

- hospitalization of a patient enrolled as an outpatient;
- prolonged hospitalization of inpatient participants;
- persistent or significant disability/incapacity at the time of study discharge;
- death.

6.1.3 Identification of an SAE requires some clinical judgment. Any questions concerning the identification and reporting of an SAE should be discussed as soon as possible with the site coordinator in the first instance, and with the FIEBRE scientific program coordinator (Heidi Hopkins), site principal investigator (PI), and/or chief investigator (CI, David Mabey) as needed.

6.1.4 AEs that do not meet criteria for "serious" may be reported by study participants. These may be recorded as a matter of routine in the participant's medical records where appropriate, and summarized on study CRFs at the Day 28 follow-up visit.

6.2 Reporting SAEs

6.2.1 Report SAEs to the FIEBRE study co-ordination centre within 24 hours of the local site being made aware of the event. (This may be done by emailing the scientific program coordinator Heidi Hopkins; or if she is not available, by emailing the program manager Amit Bhasin and/or CI David Mabey.)

6.2.2 SAEs may be reported using your site's established form (if available and/or required), or using the example template provided as an Appendix to this SOP.

6.2.3 Complete and submit the SAE form with as much detail as available at the time that you become aware of the event. Complete and submit a follow-up SAE report upon receipt of any outstanding information.

7 Documentation: FIEBRE protocol (version 2.5, 31 Jul 2018) sections 8, especially 8.4 and 8.5,
and example SAE report form (below).

FIEBRE

Febrile Illness Evaluation in a Broad Range of Endemicities

ADVERSE EVENT REPORTING FORM

Participant study ID		Site	
Participant date of birth	__ __ / __ __ / __ __	Or approximate age if not known	
Date AE/SAE reported by participant		Participant gender	
Participant date of admission		How many days had they been in the study?	
Staff member completing form			

TYPE OF SERIOUS ADVERSE EVENT	**Tick appropriate box**
Hospitalisation of a patient enrolled as an outpatient	
Prolonged hospitalisation of inpatient *(use clinical judgment and locally appropriate definition)*	
Persistent or significant disability/incapacity at time of study discharge	
Death	

DESCRIPTION - describe the SAE (attach extra sheet if more space required), including any relevant data e.g. inpatient/outpatient, blood culture results, and management

CAUSALITY - likelihood of SAE being caused by study activities

ACTIONS TAKEN where appropriate, and any ongoing concerns

Name of person completing form	Signature of person completing form	Date of form completion

Date of submission to LSHTM	Name of submitter	Signature of submitter