FIEBRE Standard Operating Procedure F.02		
Title	**Informed Consent & Assent Procedure**	
SOP Reference	***Version***	***Date of effect***
F.02	2.1.2	17 Dec 2018

SOP Development

	Name	Title	Signature	Date
Author	Heidi Hopkins	Scientific Program Coord.		
Reviewer	Kate Haigh	Clinical Governance Coord.		
Approver				

Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
31 Oct 2018	Kate Haigh		20 Nov 18
18 Dec 2018	Kate Haigh		17 Dec 18

Revision History

Version No.	Effective date	Reason for change
2.0	20 Nov 18	Updating from nasopharyngeal to pharyngeal swab
2.1.2	17 Dec 18	Correction of formatting

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: INFORMED CONSENT & ASSENT PROCEDURE

2 Purpose: To describe the procedure for obtaining informed consent *and/or assent* from potential FIEBRE study participants for their participation in the study.

3 Responsible staff: [site-specific]

4 Background & Rationale: Each participant that meets the study selection criteria must provide written informed consent before any study procedures are performed. This applies to patients and controls of all ages.

An adult participant provides informed consent for her- or himself; a child participant requires consent from a parent or guardian, and may also provide assent for her- or himself (see definitions and more detail below). If a patient is severely ill and cannot make or communicate decisions for her-/himself, the next of kin may provide consent. Study staff should conduct informed consent discussions with potential participants, parents/guardians, or next of kin, according to the individual participant's circumstances.

As part of the informed consent process, all information that is relevant to participation in the research must be discussed with the potential participant (or the parent/guardian or next of kin). The person giving consent should understand the purpose of the study, the possible risks and benefits, and what will be required during participation, so that s/he can make an informed decision about whether or not to participate in the study. Written information sheets and consent forms in English and/or the local language will be provided to each potential participant.

5 Supplies and Materials

- Information Sheet and Consent Form for study participation (in appropriate language)
- Information Sheet and Consent Form for future use of biological specimens (in appropriate language)
- Where appropriate: Informed Assent Forms for children old enough to understand study participation
- Ink pen

- Ink pad (for fingerprints)

6 Procedures:

6.1 Informed consent process

6.1.1 Informed consent must be obtained for each participant before any study procedures are performed.

6.1.2 The informed consent process is conducted by a study staff member. The statements below are guidance to the study staff member conducting the informed consent process.

6.1.3 The informed consent discussion should take place in a quiet space so that the potential participant is free to ask questions and discuss the study thoroughly. The discussion may be conducted with more than one potential participant at once, for efficiency and to assist understanding. However, each participant must have the opportunity to ask questions in private. In addition, signing or fingerprinting must take place individually.

6.1.4 If the potential participant is an adult (aged 18 or older in Malawi, Mozambique, Myanmar, and Zimbabwe; aged 16 years or older in Laos) who is not severely ill, conduct the informed consent process directly with her/him. The potential participant may choose whether or not to have other people present during the discussion.

6.1.5 If the potential participant is younger than 18 years (2 months to 17 years old), conduct the informed consent process with the child's parent or guardian. A guardian is person aged 18 years or older who can take responsibility for the child's well-being (e.g. a grandparent, an older sibling, an aunt or uncle, or other similar close relationship). If the potential participant is a child aged [8 to 17 years old; adjust age range as appropriate for each study site], s/he must also participate in the informed consent process and must give her/his assent before any study procedures are performed.

Note: Many countries recognize the right of "emancipated minors" to consent for themselves. An emancipated minor is a person younger than the legal age of adulthood (18 years, or 16 years in Laos) who has taken on adult roles and responsibilities; for example, a girl who has children, has a husband, or acts as head of household. Each study team should follow their own site's national/regulatory rules for enrolment of emancipated minors.

6.1.6 If the potential participant is severely ill and unable to give consent or assent at the time of enrolment – for example, someone

being admitted for inpatient care – you may ask their next of kin (parent/guardian in the case of a child, spouse in the case of married individuals, or other similar close relationship) to provide informed consent on behalf of the patient. Be sensitive and exercise good judgment in deciding whether and how to approach family members of a severely ill patient. In the FIEBRE study, it is important to include patients who are very ill, to learn more about what causes such illness; also, it is important to respect the needs and wishes of families at a stressful time. If/when a severely ill participant regains capacity to communicate and make decisions, ask her/him to confirm or withdraw informed consent/assent. Ensure the participant understands that s/he is free to withdraw from the study without risking access to current or future routine health care.

6.1.7 If, during the informed consent process, the potential participant decides for any reason that s/he does not want to participate in the study, return to the Screening & Enrollment Form and answer "NO" to the question "Provision of informed consent." Do not enrol the person in the study. Explain to her/him that s/he is free to continue seeking routine care at the health center.

6.2 Consent to participate in a research study

6.2.1 If the participant (or parent/guardian or next of kin) can read, give her/him a copy of the consent form for study participation to read before beginning the consent discussion. Begin the discussion after s/he has had time to read the document. If the person cannot read, read aloud and explain each section to her/him.

6.2.2 Review the entire consent form with the potential participant. For all potential participants, it is important to review all aspects of the study, including risks and benefits, and what is required for participation (including the number of study visits, the type and number of blood/pharyngeal/urine samples to be taken, the type of questions to be asked, the approximate time commitment, and the storage of samples for future use).

Answer any questions that are raised during the discussion clearly and honestly. It is important that the potential participant understands the study and the requirements of participation clearly – both so that s/he can consent or decline freely, and so that if s/he

does participate, the participation is likely to be completed in a way that is congenial and efficient for everyone involved.

6.2.3 If a person agrees to participate in the study, s/he should confirm this in the space provided on the last page of the consent form. If the person can read and write, ask her/him to print and sign her/his name, and record the date and time of signing.

If the person cannot read and write, an impartial witness must confirm that s/he has participated in the informed consent discussion, has understood the contents of the consent form, and freely agrees to participate. Any adult aged 18 years or older [or 16 in Laos?], who is not directly associated with the study, and who is able to read and write, may serve as a witness. If at all possible, the witness should be someone chosen by the participant. The witness should print the participant's name and the date in the space provided, and should observe the participant while s/he places a fingerprint in the rectangular space. The witness should then print and sign her/his name in the space provided, and record the date and time of signing.

6.2.4 As the staff member administering the consent, record your own name, and add your signature and the date.

6.3 Consent for future use of biological specimens

6.3.1 It is usually appropriate to conduct the consent discussion on study participation, and on future use of biological samples, at the same time. During the discussion, review the consent form for future use of biological samples together with the potential participant. Answer any questions clearly and honestly.

6.3.2 It is important to review all aspects of the future of samples, including: What the samples will be used for, how the samples will be identified, risks and benefits of future use of the samples, and the fact that the participant may change her/his mind about use of the samples for future research purposes.

6.3.3 If a participant consents to participate in the study, but declines storage of biological specimens for future use, s/he may still be enrolled into the study. Inform the study coordinator and/or principal investigator as soon as possible of any such cases.

6.4 Labelling consent form/s with study number

After informed consent is obtained, all selection criteria are met for study enrolment. Assign the participant a study number (see also SOP F.01). Record the number on the participant's completed consent forms.

7 **Documentation:** FIEBRE protocol (version 2.7, 15 Oct 2018) sections 7.2.2 and 7.7,
and information sheets and consent document for participation (appendix series A) and future use of biological samples (appendix series B) for:

- Adult patients
- Parents/guardians of minor patients
- Minor patients (assent)
- Adult controls
- Parents/guardians of minor controls
- Minor controls (assent)
- Next of kin of incapacitated patients