

## 1. Introduction:

This document lays down standard operational procedures (SOP) for the processes involved in the informed consent from of patients who are eligible to participate in the study titled “Hospital based surveillance of Acute Febrile Illness in India”.

## 2. Process:

2.1 In this procedure “subject/representative” means:

- An adult capable of providing consent.
- Legally authorized representative when the subject is an adult unable to give consent.
- Parents when the subject is a child or in the absence of a parent, a guardian authorized to consent on behalf of the child.

2.2 Informed consent must be given prior to collection of epidemiological and clinical data using the standard case report form (CRF)

2.3 The AFI field staffs has to explain the following procedures to the eligible subject and has to obtain written consent for enrolment in the study, explain the details in such a way that the subject/representative understands what it would be like to take part in this research study.

- Participation in the study is entirely voluntarily and patients are free to refuse to participate or to withdraw from participation at any time.
- They/their child/ward will receive standard-of-care treatment even if they decide not to participate in the study or to withdraw participation.
- Participation will involve drawing blood for 5 mL for plasma/serum at three different intervals (at enrolment, before discharge from the hospital, and at a 4 - 6-week follow-up visit). Another set of blood will be drawn in enrolment for blood cultures. Blood cultures and other appropriate tests’ reports, will be made available to the doctor and / or district health offices whoever enrol in the study.
- Participation will involve a free-of-charge; voluntary follow-up interview and blood draw 6 weeks after hospital discharge.
- Additionally a throat swab and 1-2 ml of urine will be collected from each

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subject

- Enrolled patients with symptoms of diarrhoea will have stool collected and those with vesicular rashes will have a vesicle swab collected. And those with encephalitis like presentation, CSF will be analysed for laboratory work up (Only if CSF collected and provided by the physician)
- Participation will provide additional information for their healthcare provider about the cause of their illnesses, but most diagnostic information will not be available in time to aid in their medical care.
- Description of the study and contact details of Principal Investigator will be present in the copy of informed consent form provided to the subject.

- 2.4 All informed consent procedures have to be translated into the most common languages spoken in the catchment areas of the study hospitals.
- 2.5 If the patient is ready to participate, the technician should write his name, sign on behalf of PI on the participant copy of consent form and provide to the subject/representative.
- 2.6 It is necessary to enter study ID, name and date in the informed consent form at the time of agreement.
- 2.7 Include the Study ID (There are two consent forms, one for all recruits (1-65 years of age) and one specific assent form for children 7-17 years of age. Technician should obtain these based on the age of the patient.)
- 2.8 Obtain a copy of written consent for documentation of AFI study. The recruiter should collect the subject's/representative's signature or left thumb impression in the consent form.
- 2.9 Once the informed consent is given and documented, the data collection may begin.
- 2.10 One copy of the informed consent and assent should be handed over to the participant.

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