Acute Febrile illness (In-patient) – Case Report Form

1. Subject ID number: ☐☐☐☐☐☐
2. Date of enrollment: ☐☐ / ☐☐ / ☐☐☐☐
Name:
Hospital number:
Address:
Phone number:
3. Gender: ☐ Male ☐ Female ☐ Other
4. Date of birth: ☐☐ / ☐☐ / ☐☐☐☐
5. Age in years: ☐☐ (completed years)
6. Highest education in household: ☐☐ (completed years)
7. Highest occupation category in household with code: ☐ (code- refer guidelines)
8. Type of house (refer guidelines):
9. History of enteric fever in the past 5 years: ☐ Don't know ☐ No ☐ Yes, but unconfirmed by culture ☐ confirmed
10. Have you taken typhoid vaccine anytime in the past? ☐ Yes ☐ No ☐ Don't know
11. If yes, when did you receive the typhoid vaccine? ☐☐ / ☐☐ / ☐☐☐☐
12. Name the typhoid vaccine which was taken?
13. Number of prior hospitalizations (for this illness episode): ☐☐

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14. If yes, provide details

Name of the hospital	Date of admission	Date of discharge	Diagnosis	Outcome

15. Date of onset of fever: ☐☐ / ☐☐ / ☐☐☐☐

16. Date of admission: ☐☐ / ☐☐ / ☐☐☐☐

17. Provisional diagnosis at admission:

18. Presenting symptoms (select all that apply)

☐ Fever ☐ Cough ☐ Breathlessness
☐ Abdominal pain ☐ Diarrhea ☐ Constipation
☐ Vomiting ☐ Blood in stool ☐ Jaundice
☐ Headache ☐ Seizure ☐ Altered sensorium
☐ Rash ☐ Others_____

19. Blood culture ☐ Done ☐ Not done

20. Date of blood culture ☐☐ / ☐☐ / ☐☐☐☐

21. If not done, reason:

22.A. Blood culture lab ID ☐☐☐☐☐☐☐☐☐☐

22.B. Blood culture bottle pre-weight: ☐☐.☐☐ post-weight: ☐☐.☐☐

23. Blood culture report ☐ Contamination

☐ No Growth ☐ S. Typhi ☐ S. Paratyphi A
☐ S. Paratyphi B ☐ S. Paratyphi C ☐ Others (specify) _____

24. If positive for Typhoid and/or Paratyphoid, was isolate stored: ☐ Yes ☐ No

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25. If culture isolate not stored, enter reason

26. ID number of the isolate

☐☐☐☐☐☐☐☐☐☐ - ☐☐☐☐☐☐

27. Antimicrobial susceptibility ☐ Done ☐ Not done

28. Antimicrobial susceptibility report

Name of antibiotic	S	I	R	N
Ampicillin	☐	☐	☐	☐
Chloramphenicol	☐	☐	☐	☐
Ceftriaxone	☐	☐	☐	☐
Trimethoprim/ Sulfamethoxazole	☐	☐	☐	☐
Azithromycin	☐	☐	☐	☐
Ciprofloxacin	☐	☐	☐	☐
Pefloxacin	☐	☐	☐	☐
Others (specify)	☐	☐	☐	☐

29. Additional procedures or special medications (if any)

30. Final diagnosis at discharge

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31. Investigations that support final diagnosis

Name of the investigation	Date of investigation	Result	Interpretation

32. Date of defervescence: ☐☐ / ☐☐ / ☐☐☐☐

33. Date of discharge: ☐☐ / ☐☐ / ☐☐☐☐

34. Number of days of HDU + ICU care (combined): ☐☐

35. Outcome of episode (at discharge)

☐ Recovered without complication during hospitalization

☐ Discharged with sequale ☐ Left against medical advice

☐ Referred to other hospital ☐ Death

36. Complications during this episode (select all that apply) ☐ No complication

☐ GI Bleeding ☐ GI perforation ☐ Encephalopathy

☐ Meningitis ☐ Hemodynamic shock ☐ Myocarditis

☐ Hepatitis ☐ Pneumonia ☐ Pleural Effusion

☐ Focal infection ☐ Renal impairment ☐ Others_____

37. Antibiotic given during this episode of illness ☐ Yes ☐ No

38. If yes, antibiotic history (start with first antibiotic for this episode)

Name	Dosage	Frequency	Start date	End Date

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39. Highest daily temperature since the onset of this fever episode

Date	Temperature	Remarks
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	
☐☐ / ☐☐ / ☐☐☐☐	☐☐☐ . ☐ °F	

40. Relationship of the respondent to the patient:

Data collected by:______________________ **Signature:**

Date:____/____/______

Data verified by:______________________ **Signature:**

Date:____/____/______

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General Form Filling Guidelines

Please use ink to fill all paper forms and write all text in capital letters. Use a tick mark to select check box options and leave the unselected check box options as blank. Fields that are highlighted in grey are personal health information and should not be entered on the database. Fill date in DD/MM/YYYY format unless specified otherwise, e.g. 19/01/2018. Use a single stroke across empty fields with initials and date. If consecutive fields are blank they may all be stroked out with a single stroke. If there is a filled field in between two empty fields please use two strokes. NEVER OVERWRITE an entry in the form. For corrections on the paper form, a single line drawn across the field with corrections accompanied by the initial of the person who made that change and date of change written beside each corrected field, is acceptable. ERASER OR WHITENER ARE NOT ALLOWED ON ANY CRF. The signature of the person who filled the form and date is essential. The PI or PI designate should check all the forms before it is entered on the database

Form Filling Guidelines for Acute Febrile Illness CRF

This is the Case Report Form to document the information pertaining to all hospitalized cases with a presenting complaint of fever OR having temperature greater than or equal to 38°C (100.4°F) OR has an admission diagnosis of Acute Febrile Illness in the absence of fever being a primary presenting complaint. This form will be initiated by the site investigator as soon as the consent process has been completed. The study physician will gather the information from the hospital records, from the treating physician and investigation reports. The study physician has to interview the patient/ patient's primary caregiver/ attendant to fill some of the information. If there is any discrepancy in the information on the medical records and that which is collected during the interview, please record this in the study field diary which will

be secured till the end of the study for audit purposes. This form will be complete only after the patient is discharged from the hospital. The site investigator will enter the online version of the form within 48 hrs of discharge of the study subject.

1. **Subject ID number:** A six-character unique alpha numeric subject ID will be assigned to the subject as soon as the informed consent has been obtained. <Site code (one alphabet)><one-digit Field Research Assistant (FRA) (1 or 2 or 3)><XXXX four-digit serial number>.

2. **Date of enrollment:** The date the subject was enrolled after giving written consent is entered here. This date will be day zero from which the 14th and 28th day re-contact will be calculated. This date will not be dependent on date of admission.

   Protected health information: This information is highlighted in grey and does not need to be entered in the database.

   Name: Name of the subject as given in the hospital records is documented in this field.

   Hospital number: The unique hospital number of the patient has to be documented in the field. This number should help identify patient records during re-contact

   Address: The residential address of the subject in detail should be entered here. The **village name, block name** and **pincode** should be entered on the paper form as well as on the webportal. This part of the address is important as the Health Utilization Survey to estimate incidence of typhoid will be dependent on this address. For those who are temporary residents, address for the last six months can be entered.

   Phone number: Please collect the primary contact number at which the subject can be reached. This will not be entered on to the web portal.

3. **Gender:** Select the appropriate option to mark the gender of the subject.

4. **Date of birth:** Date of birth (DD/MM/YYYY). If only the year is known and the date or month is not known, then kindly take 15th June of that year as the date of birth.

5. **Age in years:** Please enter the age of the participant, in completed years.

6. **Highest education in household:** Enter the highest education in the household, in number of completed years of education. It can be **anyone** in the household who has had the **maximum number of years of education**. E.g. failed 9th grade equals 8 years of completed education, studying 2nd year of college would be 12+1completed years=13 years of completed education. A **household,** for the purpose of this study, is considered as a group of individuals related to each other living under one roof and sharing at least the principal meal prepared from the same kitchen.

7. **Highest occupation in household:** Enter the highest occupation in the household and enter code given below for the given occupation. This pertains to the highest occupation

in the household.

Occupation categories with code

A. Child: >6 months to < 4yrs irrespective of schooling status
B. Student: any student who is not salaried or receiving a stipend.
C. Unemployed: > 4 years and not part of formal education in past 90 days (irrespective of current status)
D. Daily wage: All employed being paid daily, intermittent, weekly, seasonal, migrant, contractual-term wages.
E. Salaried: All employed being paid monthly salary for at least the past 90 days.
F. Business: All employed being involved in self-employment including business as whole or in partnership.
G. Household work: All employed in family work but not paid formally (this includes own-household work).

8. **Type of house:**

   Hut/Govt house: Construction with one room with mud walls / wooden poles and a thatched roof. Single roomed concrete houses built under the approval of state and centrally sponsored schemes are also classified as huts.

   Kutcha: Construction with more than one room with mud walls / wooden poles and a thatched roof.

   Pucca House: One which is built with a foundation, using stone or bricks with mortar and cement and having a concrete or a stone laid roof or tiled roof.

   Mansion: A large house containing more than 5 rooms (excluding kitchen & toilet)

   Mixed House: A house which has one or two of the following. Cement or mortar used for plastering of wall or floor; tiled roof

9. **History of typhoid fever in the past 5 years:** inquire about any previous history of enteric fever for the subject in the previous 5 years, enter 'yes' 'no' or 'don't know' as told by patient. Only choose culture proven enteric fever when there is documentation available for blood culture.

10. **Have you taken typhoid vaccine anytime in the past:** Check for history of receiving typhoid vaccine. Remember it is not given as part of regular government immunization in India. It can be taken only at private clinics/hospitals and will be entered in the vaccine/immunization card. Please counter check the vaccine card for details.

11. **If yes, when did you receive the typhoid vaccine:** Enter the date when patient received typhoid vaccine. If date is unknown please enter the 15th June of that year in which the vaccine was taken as the date of vaccine

12. **Name the typhoid vaccine which was taken**: Enter the name of the typhoid vaccine

which is mentioned in the vaccine card.

13. **Number of prior hospitalization (for this illness episode):** Number of previous hospitalizations for this episode of illness. 72 hrs of being afebrile indicates end of an episode.

14. **If yes, provide details:** Enter details of hospitalization for current episode in the chronological order of occurrence.

    Name of hospital: Complete this field with the name of the facility in which the study subject was hospitalized prior to this admission.

    Date of admission: Please enter the date of admission in the facility.

    Date of discharge: Please enter the date of discharge in the facility.

    Diagnosis: Please enter the diagnosis as mentioned in the discharge summary or as mentioned by the patient.

    Outcome: Please enter outcome of the hospitalization, if the patient recovered, remained ill, left against medical advice etc.

15. **Date of onset of fever:** Please document the date of onset of the fever. Counter check this with the hospital records when available.
16. **Date of admission:** Please document the date of admission to **this** health care facility.
17. **Provisional diagnosis at hospitalization**: The site investigator should enter the provisional diagnosis given by the physician at admission.
18. **Presenting symptoms (select all that apply):** Please refer to the hospital records to identify the presenting complaints of the patient and select all the signs & symptoms which are applicable. If any other symptoms are present, which are not mentioned, select 'other' and enter the name.
19. **Blood culture:** Enter if the blood culture was 'Done' or 'Not done'.
20. **Date of blood culture:** Enter the date from the hospital's main laboratory register as it is mentioned there.
21. **If not done, reason:** Enter the reason why blood culture was not done.
22. **A. Blood culture lab ID:** Enter the number from the hospital's main laboratory register as it is mentioned there.

22.B. Blood culture bottle pre and post weight: Document the weight of the culture bottle before inoculating with blood as the pre-weight and after inoculating as post-weight. Please weight the bottles on the same weighing machine both times and document the value to the second decimal place. Please ensure that the weighing machine is calibrated.

23. **Blood culture report:** Enter the culture report as mentioned in the laboratory main register. If contamination please choose the option given. If the culture grows S. Typhi along with other organisms, kindly prioritize S.Typhi and report the culture as 'S.Typhi'. If the culture grows S. Typhi along with Paratyphi, kindly enter report as 'S. Typhi'. If the culture grows other organisms, kindly choose 'others' and enter the

organism identified.

24. **If positive for Typhoid and/or Paratyphoid, was isolate stored:** enter 'Yes' or 'No'
25. **If culture isolate not stored, enter reason:** Enter reason why the culture isolate was not stored.
26. **ID number of the isolate:** Enter the laboratory serial number followed by the subject ID number on the isolate. This. Number will be used to identify the isolate in future.
27. **Antimicrobial susceptibility test (AST):** Enter if antimicrobial sensitivity test was 'Done' or 'Not done'.
28. **Antimicrobial susceptibility and resistance report**: Enter the results for the AST **done at the tier-2 hospital** in these columns. All the antibiotics mentioned and their reports should be mentioned as: S- Susceptible, I- Intermediate, R- Resistant and N- Not tested / test not completed. If AST for the given drug is not performed, enter N in all relevant columns. If AST for other drugs has been done, enter details in 'Other'.
29. **Additional procedures or special medication:** Fill this section if there are additional procedures performed or special medication given during the current episode.
30. **Final Diagnosis at discharge:** Please note down the complete final diagnosis for the current hospitalization as mentioned in the medical records.
31. **Investigations that support final diagnosis:** Enter the details of the investigations which were performed to rule out other acute febrile illness prevalent in the area.

    Name of the investigation: Enter the name of the investigation.

    Date of investigation: Enter the date when the investigation was performed.

    Result: Enter the result of the test.

    Interpretation: Enter the interpretation of the investigations that were performed.

32. **Date of defervescence**: Enter the first calendar date the subject had no fever for 24 hours, irrespective of antipyretics. i.e. if person stopped fever at 6 pm and stays afebrile for 24 hrs (6pm next day) then the next calendar day's date has to be entered.
33. **Date of discharge**: Enter the date of discharge.
34. **Number of days of HDU/ICU care**: Please document the total number of days the study subject was in the High Dependency Unit (HDU) and/or Intensive Care Unit (ICU) **during the current hospitalization**. If there wasn't a need for HDU/ICU facility care, please document this field as '00'.
35. **Outcome of the episode**: Select the appropriate outcome of episode of fever at the time of discharge.
36. **Complications**: Select all appropriate complication which occurred during this fever episode before and during hospitalization. Please **append photocopies** of documentation on how the complications were diagnosed. If there was no complication, select the given option.

Complication	Definition
Gastrointestinal bleeding	The presence of visible blood or melena in the stool with a positive fecal occult blood test
Gastrointestinal perforation	Gastrointestinal perforation in the vicinity of the terminal ileum (or ileum/cecum/colon) typical of typhoid and seen at laparotomy (if available)
Encephalopathy	Patients with any of the following aspects of altered mental status: 1. Delirium – markedly confused thinking and speech 2. Obtundation – patient who appears unconscious but can be stimulated to respond appropriately to questions and comments 3. Stuporose – patient who does not respond appropriately to any stimuli but withdraws appropriately to noxious stimuli Comatose – patients do not respond appropriately to noxious stimuli NOTE: these exclude patients with disorientation and poor short-term memory but not delirium; apathetic or lethargic without obtundation OR 4. Glasgow Coma Scale (GCS) ≤ 12 and/or Blantyre score < 5 without alternative diagnosis with CSF examination within normal limits
Meningitis	Symptoms suggestive of meningitis and an abnormal CSF examination with/without S. Typhi or S. Paratyphi A isolated from CSF culture
Hemodynamic shock	Systolic blood pressure <90 mmHg in patients ≥12 years or <80 mmHg in patients <12 years with clinical evidence of tissue hypoperfusion (i.e. abnormal state of consciousness; cold and clammy skin; constricted peripheral veins; oliguria (<20mL urine/hour) after rehydration)
Myocarditis	Abnormal cardiac rhythm or abnormal ECG as interpreted by physician; ultrasound evidence of a pericardial effusion; ventricular failure
Hepatitis	Visible jaundice and/or hepatomegaly with abnormal levels of SGOT (AST) (>400 IU/L) and/or SGPT (ALT) (>400 IU/L) or greater than 5 times the upper normal limit of liver enzyme tests
Pneumonia	Respiratory symptoms (i.e. cough, etc.) with abnormal chest X-ray infiltrates
Pleural effusion	Clinical (i.e. shortness of breath, chest pain) and radiological evidence of a pleural effusion
Focal infection	Abscess or collection at a specific site (i.e. spleen; joint; bone; etc) with S. Typhi or S. Paratyphi A isolates from drainage culture
Renal impairment	Creatinine >2 g/dL

37. **Antibiotic given during this episode of illness**: Enter 'Yes' or 'No'.
38. **If yes, antibiotic history**: All antibiotics the patient has taken for the current episode has to be entered here. This includes antibiotics taken during current episode even before hospitalization (e.g. OPD basis, given in other clinics), start with the first antibiotic given for this episode.

    Name of antibiotic: Please note the name of the antibiotic, use generic names if possible. These can also be verified with patient retained prescriptions and other hospital records for antibiotics taken for this episode.

    Dosage: Enter the per dose or per Kg body weight/ 24 hrs details.

    Frequency: Enter details of the frequency of doses as OD, BD, TID or Q6H etc. ensure this corresponds to the dose details given above.

    Start date: Enter the date when the antibiotic was started.

    End date: Enter the appropriate date when the last dose of the antibiotic was taken. In the case of continued antibiotic treatment after discharge enter the date till which the patient will be taking the medications.

39. **Highest temperature during the episode**: Please complete this field with the highest temperature recorded for the day, during the episode. The information needs to be gathered from the hospital record and entered in Fahrenheit.
40. **Relationship of respondent to the patient**: Enter the respondent's relationship to the patient, select 'not applicable' if the respondent is the patient.

Once the form is filled kindly review this and sign and enter the date when the from was finalized. The form must be verified, dated, and signed by another person involved in the study.