ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS ACUTE SYMPTOMS – (CAS)

Patient's Identification Code : _____

Introduction

This standardized Case Report Form (CRF) is the result of an ongoing effort between the World Health Organization (WHO), The Pan-American Health Organization (PAHO), Institute Pasteur (IP), and the networks of ISARIC, CONSISE PREPARE and REACTing to generate standardized clinical and epidemiological research tools.

DESIGN OF THIS CASE REPORT FORM (CRF)

There are sets of Case Report Forms (CRFs) to be used in combination for prospective cohort studies or case control studies. These sets of CRFs are to be used at admission and at discharge/going home. For any patients admitted for more than 24 hours, the Baseline and Outcome CRF and the Laboratory Results CRF can be copied and used for daily data recording.

For all studies, we recommend completing a minimum of the **Child Baseline and Outcome (CBO)** CRF, follow by **Child Acute Symptoms (CAS).** If the patient is admitted to a hospital or has further investigations, complete **Child Hospital Stay (CHS)** and **Child Laboratory Results (CLR)** CRFs. We recommend completing the Neonatal CRF and the Maternal Baseline and Outcome CRF to capture maternal and/or neonatal risk factors. If the patient is admitted to an Intensive Care Unit or Pediatric Intensive Care Unit, complete **Child Intensive Care (CIC)** as well. For follow up visit(s) complete **Child follow up visit(s) (CFU).**

Complete the outcomes sections in the **CBO** CRF once all diagnostics laboratory results and final diagnosis are available.

HOW TO USE THIS CRF

When completing the CRF modules, please make sure that:

- The patient or consultee/guardian/representative has been given information about the study and the informed consent form has been completed and signed.
- The study ID codes have been assigned for the patient as per hospital protocol and guidelines.
- The study ID codes should be filled in on all pages of paper CRF forms, all information should be kept confidential at all times, and no identifiable information is recorded on the CRFs.
- Patient's hospital ID and contact details are recorded on a separate contact list to allow later follow up. The contact forms must be kept separate from the CRFs at all times and kept in a secure location.

Each site may choose which data to collect based on available resources and the number of patients enrolled to date. Ideally, data on patients will be collected using all CRF modules as appropriate.

Sites with very low resources or very high patient numbers may select **Child Baseline and Outcome (CBO)** CRF module only. The decision is up to the site Investigators and may be changed throughout the data collection period. All high quality data are valuable for analysis.

GENERAL GUIDANCE

- The CRFs are designed to collect data obtained through patient examination, for patient or parent/guardian/representative interview and review of hospital notes.
- Patient ID codes should be filled in on all pages of paper CRF forms.
- Complete every line of every section, except for where the instructions say to skip a section based on certain responses.
- Selections with square boxes (☐) are single selection answers (choose one answer only). Selections with circles (○) are multiple selection answers (choose as many answers as are applicable).
- It is important to indicate when the answer to a particular question is not known. Please mark the 'Unknown' box if this is the case.
- Some sections have open areas where you can write additional information. To permit standardized data entry, please avoid writing additional information outside of these areas.
- We recommend writing clearly in black or blue ink, using BLOCK-CAPITAL LETTERS.
- Place an (X) when you choose the corresponding answer. To make corrections, strike through (----) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
- Please contact us, if we can help with any CRF completion questions, if you have comments and to let us know that you are using the forms. Please contact Dr Gail Carson by email: gail.carson@ndm.ox.ac.uk

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Disclaimer: These CRFs are intended for use as a standardized document for the collection of clinical data in studies investigating the Zika virus. Responsibility for use of these CRFs rests with the study investigators. ISARIC and the authors of the CRF accept no responsibility for the use of the CRF in an amended format nor for the use of the standardized CRF outside its intended purpose. *Formatting issues are in the process of being resolved. Word documents are available in order to adapt and translate the CRFs, however, there may be issues between Macs and PCs. The PDF format is also available, which should be well formatted on both systems*.

1. Geoposition	**Latitude: ____. _____**	**Longitude: ____. _____**	
2. Name of site/clinic/hospital			
If geoposition not available			
3. City/town/village:			
4. Country:			
5. Admitted to hospital *If yes: (also complete form **CHS**)*	☐ Yes ☐ No ☐ Unknown		
6. If yes, date of admission (dd/mm/yyyy)	__ / __ / 20 __	**7. Date of discharge**	__ / __ / 20 __ ☐Unknown
8. Name of hospital admitted to and town/city:			
9. Date of onset of first symptoms (dd/mm/yyyy)	__ / __ / 20 __		

1) INITIAL EXAMINATION

BASELINE OBSERVATIONS AND SIGNS AT PRESENTATION (≤24 hours of presentation)			
10. Date (dd/mm/yyyy**)**	__ / __ / 20 __ __		
11. Maximum Temperature	_____°C ☐ _____°F ☐ ☐ Unknown ☐Oral ☐Tympanic ☐Axillary ☐Anal ☐Skin		
12. Respiratory Rate	_____breaths/minute ☐ Unknown		
13. Heart Rate	_____ beats/minute ☐ Unknown		
14. Systolic Blood Pressure	_____mmHg ☐ Unknown		
15. Diastolic Blood Pressure	_____mmHg ☐ Unknown		
16. Peripheral O_2 Saturation (SpO_2)	_____ % ☐Not recorded ☐ Unknown		
17. Glasgow Coma Score (out of 15) or	___ / 15 ☐ Unknown		
18. AVPU (tick state of consciousness)	☐Alert ☐Responds to verbal stimuli ☐ Responds to pain stimuli ☐ Unresponsive		
19. Weight *	_____ ☐grams ☐pounds/ounces		
20. Height *	_____ ☐cm ☐feet/Inches		
21. Head circumference *	_____ cm		
*Plot metrics in growth curve as per your national guidelines and record the standard deviations above (indicated with "+") or below (indicated with "-") the mean for age and sex	**22. Current weight** ____ SD	**23. Current length** ____ SD	**24. Current head circumference** ____ SD
25. Weight loss	☐Yes ☐No ☐Unknown		
If yes, specify lost during this current episode of illness	_____ ☐kg ☐pounds/ounces		
26. Lymphadenopathy	☐Cervical only ☐General ☐No ☐Unknown		

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Patient's Identification Code : _____

27. Enlarged liver	☐Yes ☐No ☐Unknown	**28. Enlarged spleen**	☐Yes ☐No ☐Unknown

Note: *If further demographic or epidemiology information is required please use the complementary ZIKV CRF Epidemiology and Demographics*

2) SYMPTOMS (since first day of onset of this illness episode)

29. Amnesia	☐Yes ☐No ☐Unknown
30. Confusion/disorientation	☐Yes ☐No ☐Unknown
31. Altered behavior or personality	☐Yes ☐No ☐Unknown
32. Headache	☐Mild ☐Moderate ☐Severe ☐No ☐Unknown
33. Photophobia	☐Yes ☐No ☐Unknown
34. Neck stiffness	☐Yes ☐No ☐Unknown
35. Seizures	☐General ☐Focal ☐No ☐Unknown
36. Paralysis	☐General ☐Ascending ☐No ☐Unknown
If yes, please describe affected body parts and if progressive: ☐Yes ☐No	
37. Weakness	☐General ☐Focal ☐No ☐Unknown o Power test o Patient complaint
If focal, please describe affected body parts and if progressive: ☐Yes ☐No	
38. Oromotor dysfunction	☐Yes ☐No ☐Unknown
39. Movement disorder	☐Yes ☐No ☐Unknown
40. Shortness of breath	☐Yes ☐No ☐Unknown
41. Sore throat	☐Yes ☐No ☐Unknown
42. Cough	☐Yes ☐No ☐Unknown
43. Rhinitis	☐Yes ☐No ☐Unknown
44. Chest pain	☐Yes ☐No ☐Unknown
45. Back pain	☐Yes ☐No ☐Unknown
46. Myalgia	☐Yes ☐No ☐Unknown
47. Arthralgia	☐Yes ☐No ☐Unknown
48. Joint swelling	☐Yes ☐No ☐Unknown
If yes, specify all affected joints:	o Fingers o Toes o Knee o Elbow o Other ☐ yes ☐ no if yes specify:_____
49. Conjunctivitis	☐Yes ☐No ☐Unknown
If yes, specify if:	☐Purulent ☐Non-purulent
50. Retro-orbital pain	☐Yes ☐No ☐Unknown
51. Periorbital pain	☐Yes ☐No ☐Unknown
52. Rash	☐Yes ☐No ☐Unknown

If yes, please check box for type of rash and specify location:		**Spread of the rash:**
53. Maculopapular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
54. Erythematous rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____

Patient's Identification Code : _____

55. Non blanching rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
56. Vesicular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
57. Erythema migrans	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
58. Pruritic rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
59. Petechial or purpuric rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
60. Bruising/ ecchymosis	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
61. If other type of rash, please specify type and spread:	Type: ○ Face ○ Torso ○ Upper limbs ○ Lower limbs ○ Palms ○ Other:	
62. Pruritus	☐Yes ☐No ☐Unknown	
If yes, specify:	☐ Generalized ☐ Localized	
63. Jaundice	☐Yes ☐No ☐Unknown	
64. Sign of insect bites	☐Yes ☐No ☐Unknown	
65. Bleeding	☐Yes ☐No ☐Unknown	
If yes, please state source:	○ Bruising ○ Gums ○ Nose ○ Hematemesis ○ Melena or fresh per rectum ○ Hematuria ○ Vaginal ○ Other, specify:	
66. Mouth ulcers	☐Yes ☐No ☐Unknown	
67. Diarrhea	☐Yes ☐No ☐Unknown	
68. Vomiting/nausea	☐Yes ☐No ☐Unknown	
69. Stomach pain	☐Yes ☐No ☐Unknown	
70. Other (specify):		

3) Treatment

Medications administered (from onset of symptoms)

List all medications administered for acute symptoms. Use generic names and list all treatment given to the patient for this illness episode from date of onset.

Type of medication	Name of medication and dose (generic name)	Start date (dd/mm/yyyy)	Number of days	Route of administration
71. Antibiotics ☐Yes ☐No				☐IV ☐Oral ☐IM
72. Antivirals ☐Yes ☐No				☐IV ☐Oral
73. Anti-inflammatory/ Antipyretics ☐Yes ☐No				☐IV ☐Oral

Patient's Identification Code : _____

74. Corticosteroids ☐Yes ☐No				☐IV ☐Oral ☐Topical ☐Inhaled
75. Anticonvulsants ☐Yes ☐No				☐IV ☐Oral
76. Immunoglobulins ☐Yes ☐No				☐IV ☐Oral ☐Subcut
77. Other (specify):				☐IV ☐Oral ☐Topical ☐Inhaled ☐Subcut ☐PR ☐IM ☐Sublingual
Other (specify):				☐IV ☐Oral ☐Topical ☐Inhaled ☐Subcut ☐PR ☐IM ☐Sublingual
Other (specify):				☐IV ☐Oral ☐Topical ☐Inhaled ☐Subcut ☐PR ☐IM ☐Sublingual
Other (specify):				☐IV ☐Oral ☐Topical ☐Inhaled ☐Subcut ☐PR ☐IM ☐Sublingual

4) TRANSFER TO OTHER HOSPITAL

78. Was the patient transferred to another hospital?	☐Yes ☐No ☐Unknown
79. If yes, please state name of the hospital and city (address if possible):	Hospital name: City/Town/Village:
80. Please state reason for transfer:	

*If admitted to intensive care unit, please also complete form **CIC***

5) CASE REPORT FORM COMPLETED BY

Name and role			
Signature		**Date** (dd/mm/yyyy)	