ZIKA VIRUS CASE REPORT FORMS – MATERNAL ACUTE SYMPTOMS – (MAS)

Mother's Identification Code : _____ Neonate'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 two sets of Case Report Form (CRF) to be used - Neonate and Maternal. The CRFs are 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 **Maternal Baseline and Outcome (MBO)** and **Neonate Baseline and Outcome (NBO)** CRFs, follow by **Maternal Laboratory Results (MLR)** and **Neonate Laboratory Results (NLR)** CRFs for all neonates post-delivery. If the mother and/or neonate is admitted to an Intensive Care Unit or Pediatric Intensive Care Unit, complete **Maternal Intensive Care (MIC)**, and/or **Neonate Intensive Care (NIC)** as well.

For pregnant women presenting with acute symptoms, complete **Maternal Acute Symptoms (MAS)**, and for all studies complete **Maternal Antenatal Care (MAC).**

Complete the outcomes sections in CRFs **MBO** and **NBO** 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 mother 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 both mother/pregnant woman and neonate 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.
- Patients' 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 (neonate and mother) will be collected using all CRF modules as appropriate.

Sites with very low resources or very high patient numbers may select **Maternal and Neonatal Baseline and Outcome** CRF modules. The decision is up to the Site Investigators and may be changed throughout the data collection period. All high quality data is valuable for analysis.

GENERAL GUIDANCE

- The CRFs are designed to collect data obtained through patient examination, through parent/guardian/representative (for neonates) interview and review of hospital notes.
- Patient ID codes should be filled in on all pages of paper CRF forms (neonate and mother).
- 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 keep all of the sheets for each study subject together e.g. with a staple or in a folder that is unique to the patient.

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- 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

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	☐ 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) 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)	_____ % ☐ 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	_____ ☐ kg ☐ pounds/ounces
20. Height	_____ ☐ cm ☐feet/inches
21. Weight loss	☐Yes ☐No ☐Unknown
If yes, specify lost during this current episode of illness	_____ ☐kg ☐pounds/ounces
22. Lymphadenopathy	☐Cervical only ☐General ☐No ☐Unknown
23. Enlarged liver	☐Yes ☐No ☐Unknown
24. Enlarged spleen	☐Yes ☐No ☐Unknown

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

25. Amnesia	☐Yes ☐No ☐Unknown

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26. Confusion/disorientation	☐Yes ☐No ☐Unknown	
27. Altered behavior or personality	☐Yes ☐No ☐Unknown	
28. Headache	☐Mild ☐Moderate ☐Severe ☐No ☐Unknown	
29. Photophobia	☐Yes ☐No ☐Unknown	
30. Neck stiffness	☐Yes ☐No ☐Unknown	
31. Seizures	☐General ☐Focal ☐No ☐Unknown	
32. Paralysis	☐General ☐Ascending ☐No ☐Unknown	
If yes, describe affected body parts and if progressive: ☐Yes ☐No		
33. Weakness	☐General ☐Focal ☐No ☐Unknown ○Power test ○Patient complaint	
If focal, please describe affected body parts and if progressive: ☐Yes ☐No		
34. Oromotor dysfunction	☐Yes ☐No ☐Unknown	
35. Movement disorder	☐Yes ☐No ☐Unknown	
36. Shortness of breath	☐Yes ☐No ☐Unknown	
37. Sore throat	☐Yes ☐No ☐Unknown	
38. Cough	☐Yes ☐No ☐Unknown	
39. Rhinitis	☐Yes ☐No ☐Unknown	
40. Chest pain	☐Yes ☐No ☐Unknown	
41. Back pain	☐Yes ☐No ☐Unknown	
42. Myalgia	☐Yes ☐No ☐Unknown	
43. Arthralgia	☐Yes ☐No ☐Unknown	
44. Joint swelling	☐Yes ☐No ☐Unknown	
If yes, specify all affected joints:	○ Fingers ○ Toes ○ Knee ○ Elbow ○ Other (specify):	
45. Conjunctivitis	☐Yes ☐No ☐Unknown	
If yes, specify if:	☐Purulent ☐Non-purulent	
46. Retro-orbital pain	☐Yes ☐No ☐Unknown	
47. Periorbital pain	☐Yes ☐No ☐Unknown	
48. Rash	☐Yes ☐No ☐Unknown	
If yes, please check box for type of rash and specify location:		**Spread of the rash:**
49. Maculopapular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
50. Erythematous rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
51. Non blanching rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
52. Vesicular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
53. Erythema migrans	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
54. Pruritic rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
55. Petechial or purpuric rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____

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

3) MEDICATIONS ADMINISTERED (from onset of first symptoms of this illness episode)

List all medications administered for acute symptoms:
Use generic names, list all treatment given to the mother 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
67. Antibiotics ☐Yes ☐No				☐IV ☐Oral ☐IM
68. Antivirals ☐Yes ☐No				☐IV ☐Oral
69. Anti-inflammatories/ Antipyretics ☐Yes ☐No				☐IV ☐Oral
70. Corticosteroids ☐Yes ☐No				☐IV ☐Oral ☐Topical ☐Inhaled
71. Anticonvulsants ☐Yes ☐No				☐IV ☐Oral
72. Immunoglobulins ☐Yes ☐No				☐IV ☐Oral ☐Subcut
73. Other (specify):				☐IV ☐Oral ☐Topical Inhaled ☐Subcut ☐PR ☐IM ☐Sublingual
Other (specify):				☐IV ☐Oral ☐Topical ☐Inhaled ☐Subcut ☐PR ☐IM

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				☐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

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

If patient was admitted to intensive care, please also complete the ZIKV CRF- Maternal Intensive Care (MIC).

5) CASE REPORT FORM COMPLETED BY

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