ZIKA VIRUS CASE REPORT FORMS – NEONATE LABORATORY RESULTS – (NLR)

Neonate's Identification Code : _____ Mother'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.

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- 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.
- 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) LABORATORY RESULTS NEONATE (samples taken ≤ 24 hours after delivery/presentation)

Please record all values that are available as part of the clinical care for all neonates included in the study.

Please use standard (SI) units if possible. Please specify the unit used for each result. For repeat sampling copy page use the most abnormal value per day and ensure date and patient ID is indicated on each form.

1. Date of sampling (dd/mm/yyyy)	__ / __ / 20 __		
Test		**Value**	**Specify unit, if other specify unit used.**
Inflammatory markers			
2. C-reactive protein	☐Yes ☐Not done ☐Unknown		☐mg/L ☐other:_____
3. Erythrocyte sedimentation rate	☐Yes ☐Not done ☐Unknown		☐mm/hr ☐other:_____
4. Procalcitonin	☐Yes ☐Not done ☐Unknown		☐ng/mL ☐other:_____
Hematology			
5. Hemoglobin	☐Yes ☐Not done ☐Unknown		☐g/L ☐g/dL ☐other:_____
6. Hematocrit	☐Yes ☐Not done ☐Unknown		☐% ☐other:_____
7. RBC count	☐Yes ☐Not done ☐Unknown		☐x10^9/L ☐x10^3/µL ☐other:_____
8. MCV	☐Yes ☐Not done ☐Unknown		☐µm^3 ☐other:_____
9. White blood cell count	☐Yes ☐Not done ☐Unknown		☐x10^9/L ☐x10^3/µL ☐other:_____
10. Neutrophils	☐Yes ☐Not done ☐Unknown		☐10^3/mm^3 ☐**%** ☐other:_____
11. Lymphocytes	☐Yes ☐Not done ☐Unknown		☐10^3/mm^3 ☐**%** ☐other:_____
12. Monocytes	☐Yes ☐Not done ☐Unknown		☐10^3/mm^3 ☐**%** ☐other:_____
13. Eosinophils	☐Yes ☐Not done ☐Unknown		☐10^3/mm^3 ☐**%** ☐other:_____
14. Basophils	☐Yes ☐Not done ☐Unknown		☐10^3/mm^3 ☐**%** ☐other:_____
15. Platelets	☐Yes ☐Not done ☐Unknown		☐x10^9/L ☐x10^3/µL ☐other:_____
16. APTT	☐Yes ☐Not done ☐Unknown		☐seconds
17. PT (seconds)	☐Yes ☐Not done ☐Unknown		☐seconds
18. Blood film	☐Yes ☐Not done ☐Unknown		Describe results: _____
Biochemistry			
19. Urea nitrogen	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐mg/dL ☐other:_____
20. Creatinine	☐Yes ☐Not done ☐Unknown		☐µmol/L ☐mg/dL ☐other:_____
21. Sodium	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐other:_____
22. Potassium	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐other:_____
23. Total protein	☐Yes ☐Not done ☐Unknown		☐g/dL ☐other:_____
24. Albumin	☐Yes ☐Not done ☐Unknown		☐g/L ☐other:_____

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25. Bilirubin	☐Yes ☐Not done ☐Unknown		☐µmol/L ☐mg/dL ☐other:_____
26. AST/SGOT	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
27. ALT/SGPT	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
28. GGT	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
29. ALP	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
30. Calcium	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐other:_____
31. Phosphate	☐Yes ☐Not done ☐Unknown		☐mg/dL ☐other:_____
32. Magnesium	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐other:_____
33. Amylase	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
34. Glucose	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐mg/dL ☐other:_____
35. Creatine kinase	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
36. Other biochemistry result (specify):	☐Yes ☐Not done ☐Unknown		☐Unit:_____
Other biochemistry result (specify):	☐Yes ☐Not done ☐Unknown		☐Unit:_____
If yes , describe results:			

2) CSF SAMPLE (if available as part of clinical care)

37. Lumbar puncture performed ☐Yes ☐No ☐Unknown

If yes, complete tables below. If no CSF sample, skip to section 3.

38. Date of lumbar puncture (dd/mm/yyyy):___ / ____ / 20 ___

39. CSF appearance	☐Clear and colorless ☐Cloudy ☐Blood stained ☐Frank blood/traumatic tap ☐Unknown
40. Gram stain	☐ No organisms seen ☐ Organisms seen ☐Not done If organism seen, describe the gram morphology:

*Must be taken within 4 hours of the lumbar puncture. Record capillary blood glucose measurement if laboratory plasma glucose not requested.

Test	Value	Specify units	
41. CSF protein		☐mg/dl	☐other: ___
42. CSF glucose		☐mmol/l	☐other: ___
43. Plasma glucose at time of lumbar puncture*		☐mmol/l	☐other: ___
44. CSF RBC count		☐per mm^3	☐other: ___
45. CSF WBC count		☐per mm^3	☐other: ___
46. WBC Lymphocytes		☐%	☐other: ___
47. WBC Neutrophils		☐%	☐other: ___

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3) PATHOGEN TESTING

Record all pathogen tests carried out for differential diagnosis. Please record all results available from local, and/or regional reference laboratories. For additional sample type, add to other, or copy in additional rows as needed.

Sample type	Pathogen	Date of sampling (dd/mm/yyyy)	Method	Results	Methods/Assays used	Comments
48. Guthrie test (dried blood spot)		__/__/20__	☐PCR ☐Serology ☐Other: _____			
Guthrie test (dried blood spot)		__/__/20__	☐PCR ☐Serology ☐Other: _____			
49. Blood		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Blood		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
50. Urine		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Urine		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
51. ☐Saliva swab **52. ☐Throat swab** **53. ☐Nasal swab**		__/__/20__	☐PCR ☐Culture ☐Other: _____			
54. CSF		__/__/20__	☐PCR ☐Culture ☐Serology			

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			☐Microscopy ☐Other: _____			
CSF		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
55. Placenta		__/__/20__	☐PCR ☐Culture ☐Other: _____			
56. Amniotic fluid		__/__/20__	☐PCR ☐Culture ☐Other: _____			
57. Other (specify):		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Other (specify):		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Other (specify):		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Other (specify):		__/__/20__	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			

4) CASE REPORT FORM COMPLETED BY

Name and role			
Signature		**Date** (dd/mm/yyyy)	____ / ____ / 20 ___

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