ZIKA VIRUS CASE REPORT FORMS – MATERNAL INTENSIVE CARE – (MIC)

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.

Mother's Identification Code : _____ **Neonate's Identification Code : _____**

- 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. Date of admission to intensive care unit (dd/mm/yyyy)	__ / __ / 20___
2. Reason for admission to intensive care	☐ Organ failure ☐ Monitoring ☐ Other
3. If organ failure specify organs	○ Cardiovascular ○ Respiratory ○ Renal ○ Hepatic ○ Coagulopathy ○ Unknown ○ Other (specify):
4. Date of discharge from intensive care (dd/mm/yyyy)	__ / __ / 20___
5. Discharged to	☐ General ward ☐ Other hospital ☐ Home ☐ Deceased ☐ Unknown
6. If discharged to another hospital Name & Location of hospital:	

1) CRITICAL CARE (record the most abnormal result during admission to high dependency)

Respiratory assessment	
7. Oxygen saturation (SaO$_2$)	____% ☐ Room air ☐ Supplementary oxygen
8. FiO2 (0.21-1.0):	_____or _____L/min
9. PaO$_2$	____ kPa / mmHg ☐ Venous ☐ Capillary ☐ Arterial sample
10. PaCO$_2$	____ kPa / mmHg ☐ Venous ☐ Capillary ☐ Arterial sample
11. HCO$_3$	____ mmol/L ☐ Venous ☐ Capillary ☐ Arterial sample
12. Base Excess	____ mmol/L ☐ Venous ☐ Capillary ☐ Arterial sample
13. pH	____ ☐ Venous ☐ Capillary ☐ Arterial sample
Respiratory support	
14. High flow O$_2$	☐ Yes ☐ No *If yes, start date?* [dd/mm/yyyy] __ / __ / ____
15. Non-invasive ventilation	☐ Yes ☐ No *If yes, start date?* [dd/mm/yyyy] __ / __ / ____
16. Intubation	☐ Yes ☐ No *If yes, intubation date?* [dd/mm/yyyy] __ / __ / ____
17. ECMO	☐ Yes ☐ No *If yes, start date?* [dd/mm/yyyy] __ / __ / ____
Cardiovascular support	
18. Venous access	☐ Yes ☐ No *If yes* ○ Peripheral ○ Central venous ○ Interosseous
19. Vasopressors / inotropes	☐ Yes ☐ No *If yes, start date?* [dd/mm/yyyy] __ / __ / ____
Renal support	
20. Urine output	____ ml/hr Mother's Weight ____ kg
21. Hemofiltration	☐ Yes ☐ No *If yes, start date?* [dd/mm/yyyy] __ / __ / ____

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2) MEDICATIONS ADMINISTERED (while in intensive care/high dependency)

22. List medications administered from date of admission. Use generic names and include antibiotics, antivirals, corticosteroids, immunoglobulin, anticonvulsants, fluids and others.						
Type of medication	**Name of medication** (generic name)	**Dose** (for fluids indicate volume)	**Frequency** (a day)	**Start date** (dd/mm/yyyy)	**Number of days**	**Route of administration**
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral

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						☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, specify:

If there isn't enough space photocopy this page for additional sheets

3) CASE REPORT FORM COMPLETED BY

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