ZIKA VIRUS CASE REPORT FORM – NEONATE INTENSIVE CARE

Neonate identification code: _____ Birth mother's identification code: _____

DESIGN OF THIS CASE REPORT FORM (CRF)

There are two sets of Case Report Form (CRF) to be used in combination - 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 use 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 (**1) Neonate Baseline and Outcome** CRF and **(2) Neonate Laboratory Results** CRFs for all Neonates post – delivery. If the neonate is admitted to an Intensive Care Unit or Paediatric Intensive Care Unit, complete (**3) Neonate Intensive Care** as well.

For all studies complete the **(4) Maternal Baseline and Outcome**, **(5) Maternal Laboratory Results**, and **(6) Maternal Antenatal Care** CRFs as well. For pregnant women presenting with acute symptoms, complete **(7) Maternal Acute Symptoms**, and (**8) Maternal Intensive Care** if the patient is admitted to Intensive Care Unit.

Complete the outcomes sections in CRFs (1) and (4) 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 observational study and the informed consent form has been completed and signed.
- The study ID codes will be 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 patient identifiable information is recorded on the CRFs.
- Patients' hospital ID and contact details should be 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 keep in a secure location.

Each site may choose the amount of 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 NEONATE/MATERNAL 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 CRF is designed to collect data obtained through patient examination, for neonate through parent/guardian/representative 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 know 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 standardised 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 a single woman and neonate included in the study together e.g. with a staple or in a folder that is unique to the patient.
- Please contact us at update 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 standardised 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 standardised 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 types of machines*.

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Neonate identification code: _____ **Birth mother's identification code**: _____

Date of admission to intensive care unit (dd/mm/yyyy)	__ / ___ / 20___
Reason for admission or transfer to intensive care	
Date of discontinuation of critical care (dd/mm/yyyy)	__ / ___ / 20___
Discharged to	☐General ward ☐Another hospital ☐Home/normal residency ☐Deceased
If discharged to another hospital, please state name of hospital and city	

1) CRITICAL CARE SUPPORT

CRITICAL CARE (Record the most abnormal value in the first 24 hours):

1. Mechanical respiratory support? ☐Yes ☐No ☐Unknown

If Yes, what type? ☐ Intubation ☐Non-invasive mechanical ventilationP ☐High flow O_2

☐Others (please specify): _____

If Yes, when was it commenced (dd/mm/yyyy**)?** ____/_____/ 20 ___

FiO_2 *(0.21-1.0):* _____or _____L/min

PaO_2 _____ ☐kPa *or* ☐mmHg **Oxygen saturation***:*_____ % on: ☐Room air ☐Supplemental Oxygen[1]

Line in situ? ☐Yes ☐No
If Yes: ☐Peripheral ☐Central venous ☐Intraosseous

2. Any vasopressor/inotropic support? ☐Yes ☐No ☐Unknown

If Yes, when was it commenced (dd/mm/yyyy**):** ____/_____/ 20 ___
Date of discontinuation (dd/mm/yyyy**):** ____/_____/ 20 ___

3. Haemofiltration ☐Yes ☐No ☐Unknown

If Yes, when was it commenced (dd/mm/yyyy**)?** ____/_____/ 20 ___

4. ECMO ☐Yes ☐No ☐Unknown

If Yes, when was it commenced (dd/mm/yyyy**)?** ____/_____/ 20 ___

5. Urine output _____ ☐mL/kg/h ☐other unit(specify): _____

1 Includes invasive or non-invasive mechanical ventilation, oxygenation (O_2) via facemask/nasal prongs/hood

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2) MEDICATIONS AND SUPPORT

List medications administered within 24 hours of delivery: Use generic names. Include antibiotics, antivirals, corticosteroids, immunoglobulin, anticonvulsants, fluids and others.

Type of medication	**Name of medication** (generic name)	**Dose and frequency** (for fluids indicate volume/day)	**Start date** (dd/mm/yyyy)	**Number of days duration**	**Route of administration**
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
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					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal
					☐IV ☐Oral ☐Rectal

3) CASE REPORT COMPLETED BY

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