ZIKA VIRUS CASE REPORT FORM – NEONATE LABORATORY RESULTS

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

DESIGN OF THIS CASE REPORT FORM (CRF)

There are two sets of Case Report Forms (CRFs) to be used in combination - Neonate and Maternal. The CRFs are to be used in combination for prospective or retrospective 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 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*.

ZIKA VIRUS CASE REPORT FORM – NEONATE LABORATORY RESULTS

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

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

Please record all values that are available as part of routine 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 and ensure date and patient ID is indicated on each form.

Date of sampling (dd/mm/yyyy):	**__ / __ / 20 __**			
Test	**Value**	**Specify unit, if other specify unit used.**		
C-reactive protein		☐mg/L		☐other:_____
Erythrocyte sedimentation rate		☐mm		☐other:_____
Procalcitonin		☐ng/mL		☐other:_____
Hemoglobin		☐g/L	☐g/dL	☐other:_____
Hematocrit		☐%		☐other:_____
White blood cell count		☐x10^9/L	☐x10^3/µL	☐other:_____
Neutrophils		☐**10^3/mm^3**	☐**%**	☐other:_____
Lymphocytes		☐**10^3/mm^3**	☐**%**	☐other:_____
Monocytes		☐**10^3/mm^3**	☐**%**	☐other:_____
Eosinophils		☐**10^3/mm^3**	☐**%**	☐other:_____
Basophils		☐**10^3/mm^3**	☐**%**	☐other:_____
MCV		☐µm^3		☐other:_____
RBC count		☐x10^9/L *or*	☐x10^3/µL	☐other:_____
Platelets		☐x10^9/L *or*	☐x10^3/µL	☐other:_____
APTT		☐seconds		
PT (seconds)		☐seconds		
Urea nitrogen		☐mmol/L	☐mg/d	☐other:_____
Albumin		☐g/L		☐other:_____
Sodium		☐mEq/L		☐other:_____
Potassium		☐mEq/L		☐other:_____
Calcium		☐mmol/L		☐other:_____
Phosphate		☐mg/dL		☐other:_____
Magnesium		☐mmol/L		☐other:_____
Total protein		☐g/dL		☐other:_____
Creatinine		☐µmol/L	☐mg/dL	☐other:_____
Glucose		☐mmol/L	☐mg/dL	☐other:_____
Amylase		☐U/L		☐other:_____
Bilirubin		☐µmol/L	☐mg/dL	☐other:_____
AST/SGOT		☐U/L		☐other:_____
ALT/SGPT		☐U/L		☐other:_____
ALP		☐U/L		☐other:_____
GGT		☐U/L		☐other:_____
Creatine kinase		☐U/L		☐other:_____
Other biochemistry result (specify):		☐Unit:_____		
Other biochemistry result (specify):		☐Unit:_____		

ZIKA VIRUS CASE REPORT FORM – NEONATE LABORATORY RESULTS

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

Blood film results	☐Yes ☐Not done ☐Unknown
If yes , describe results:	

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

Lumbar puncture performed ☐Yes ☐No ☐Unknown

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

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

Test	**Please record value below**	**Specify unit used**	**If other unit used, specify unit here**
CSF glucose		☐mmol/l	
Plasma glucose at time of lumbar puncture*		☐mmol/l	
CSF WBC count		☐per mm^3	
CSF RBC count		☐per mm^3	
Lymphocytes		☐%	
Neutrophils		☐%	
CSF protein		☐mg/dl	

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

CSF appearance	☐Clear and colourless ☐Cloudy ☐Blood stained ☐Unknown
Gram stain	☐Negative ☐Positive ☐Not done

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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**	**Comments and methods/assays used**
Blood		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		
Blood		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		
Blood (dried blood spot)		__/__/20___	☐PCR ☐Serology ☐Other: _____		
Blood (dried blood spot)		__/__/20___	☐PCR ☐Serology ☐Other: _____		
Urine		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		
Urine		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		
☐Saliva swab **☐Throat swab**		__/__/20___	☐PCR ☐Culture ☐Other: _____		
CSF		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		
CSF		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		

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Placenta		__/__/20___	☐PCR ☐Culture ☐Other: _____		
Amniotic fluid		__/__/20___	☐PCR ☐Culture ☐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: _____		
Other (specify):		__/__/20___	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____		

4) CASE REPORT FORM COMPLETED BY

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