ZIKA VIRUS CASE REPORT FORM – MATERNAL ACUTE SYMPTOMS

Mother's identification code: _____ Neonate ID 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 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 (**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 kept 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*.

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Geoposition	**Latitude:** ___ _ . _____	**Longitude:** ___ _ . _____
Name of site/clinic/hospital		
If geoposition not available:		
City/town/village:		
Country:		
Admitted to hospital	☐ Yes ☐ No ☐ Unknown	
If yes, date of admission (dd/mm/yyyy)	__ / __ / 20 __	**Date of discharge** __ / __ / 20 __ ☐Unknown
Name of hospital admitted to and town/city:		
Date of onset of first symptoms (dd/mm/yyyy)	__ / __ / 20 __	

1) BASELINE OBSERVATIONS AND SIGNS AT PRESENTATION (≤24 hours of presentation)

BASELINE OBSERVATIONS			
DATE (dd/mm/yyyy)		__ / __ / 20 __ __	
Maximum Temperature		___°C ☐Oral ☐Tympanic ☐Axillary ☐Anal ☐Skin	
Respiratory Rate		_____breaths/minute	
Heart Rate		_____beats/minute	
Systolic Blood Pressure		_____mmHg	
Diastolic Blood Pressure		_____mmHg	
Peripheral O_2 Saturation (SpO_2)		_____ % ☐Not recorded	
Glasgow Coma Score (out of 15)		___ / 15	
Lymphadenopathy		☐Cervical only ☐General ☐No ☐Unknown	
Enlarged liver	☐Yes ☐No ☐Unknown	**Enlarged spleen**	☐Yes ☐No ☐Unknown

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

Headache	☐Mild ☐Moderate ☐Severe ☐No
Periorbital pain	☐Yes ☐No ☐Unknown
Photophobia	☐Yes ☐No ☐Unknown
Neck stiffness	☐Yes ☐No ☐Unknown
Seizures	☐General ☐Focal ☐No ☐Unknown
Paralysis	☐General ☐Ascending ☐No ☐Unknown
If yes, please describe affected body parts and if progressive:	

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Weakness	☐General ☐Focal ☐No ☐Unknown ○Power test ○Patient complaint	
If focal, please describe affected body parts and if progressive:		
Shortness of breath	☐Yes ☐No ☐Unknown	
Chest pain	☐Yes ☐No ☐Unknown	
Oromotor dysfunction	☐Yes ☐No ☐Unknown	
Movement disorder	☐Yes ☐No ☐Unknown	
Amnesia	☐Yes ☐No ☐Unknown	
Confusion/disorientation	☐Yes ☐No ☐Unknown	
Altered behavior or personality	☐Yes ☐No ☐Unknown	
Diarrhoea	☐Yes ☐No ☐Unknown	
Vomiting/nausea	☐Yes ☐No ☐Unknown	
Stomach pain	☐Yes ☐No ☐Unknown	
Back pain	☐Yes ☐No ☐Unknown	
Myalgia	☐Yes ☐No ☐Unknown	
Arthralgia	☐Yes ☐No ☐Unknown	
Joint swelling	☐Yes ☐No ☐Unknown	
If yes, specify all affected joints:	☐Fingers ☐Toes ☐Knee ☐Elbow ☐Other:___	
Sore throat	☐Yes ☐No ☐Unknown	
Cough	☐Yes ☐No ☐Unknown	
Conjunctivitis	☐Yes ☐No ☐Unknown	
If yes, specify if:	☐Purulent ☐Non-purulent	
Rash	☐Yes ☐No ☐Unknown	
If yes, please check box for type of rash and specify location:		**Spread of the rash:**
Maculopapular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal
Erythematous rash	☐Yes ☐No	☐Centrifugal ☐Centripetal
Non blanching rash	☐Yes ☐No	☐Centrifugal ☐Centripetal
Vesicular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal
Erythema migrans	☐Yes ☐No	☐Centrifugal ☐Centripetal
Pruritic rash	☐Yes ☐No	☐Centrifugal ☐Centripetal
Petechial or purpuric rash	☐Yes ☐No	☐Centrifugal ☐Centripetal
Bruising/ ecchymosis	☐Yes ☐No	☐Centrifugal ☐Centripetal
If other type of rash, please specify:		
Sign of insect bites	☐Yes ☐No ☐Unknown	
Bleeding	☐Yes ☐No ☐Unknown	
If yes, please state source (e.g. urine, stool):		

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PREPARE

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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** (generic name)	**Start date** (dd/mm/yyyy)	**Number of days duration**	**Route of administration**
Antibiotics ☐Yes ☐No				☐IV ☐Oral
				☐IV ☐Oral
Antivirals ☐Yes ☐No				☐IV ☐Oral
				☐IV ☐Oral
Corticosteroids ☐Yes ☐No				☐IV ☐Oral ☐Topical ☐Inhaled
Anticonvulsants ☐Yes ☐No				☐IV ☐Oral
Anti-inflammatory (e.g. NSAIDs) ☐Yes ☐No				☐IV ☐Oral
Immunoglobulins ☐Yes ☐No				☐IV ☐Oral
Other (specify):				☐IV ☐Oral
Other (specify):				☐IV ☐Oral
Other (specify):				☐IV ☐Oral
Other (specify):				☐IV ☐Oral

4) TRANSFER TO OTHER HOSPITAL

Was the patient transferred to another hospital?	☐Yes ☐No ☐Unknown
If yes, please state name of the hospital and city (address if possible):	
Please state reason for transfer:	

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

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5) CASE REPORT FORM COMPLETED BY

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