ZIKA VIRUS CASE REPORT FORM - MATERNAL BASELINE AND OUTCOME

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 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 ketp 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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INCLUSION CRITERIA

Define as appropriate for each study and as per latest national guidelines.
Ensure informed consent.

Date and time of consent (dd/mm/yyyy**):** ___ ___ / ___ ___ / _2_ _0_ __ ___ Time: __ __: __ __hours

Signature of person taking consent: _____

Print name and job role: _____

Name of site/clinic/hospital		
Geoposition	**Latitude** ___ . _____	**Longitude** ___ . _____
If geoposition not available, state location below		
City/town		
Country		
Acute symptoms in pregnant mother	☐Yes ☐No If yes, please also complete the Maternal Acute Symptoms CRF	

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Mother's identification code: _____ **Neonate ID code**: _____

1) MATERNAL DEMOGRAPHICS

Date of birth (dd/mm/yyyy)	__ / ____ / _____				
Ethnicity (according to national guidelines)					
Home city/town /village during pregnancy, state all during this pregnancy					
City/town/village			**Date from** (mm/yyyy)	**To** (mm/yyyy)	
Occupation					
Height			☐cm ☐other unit (specify):		
Weight (prior to pregnancy, specify or estimate):		☐kg ☐other unit:	**Current weight**		☐kg ☐other unit:
Familial genetic conditions on maternal or paternal side	☐Yes ☐No ☐Unknown		**If yes, specify:**		
Number of previous pregnancies (excluding present pregnancy)			**Number of previous births after 22 weeks' gestation**		
Have any previous babies been (tick all that apply):	☐Preterm (<37 weeks' gestation) ☐Stillborn or perinatal deaths ☐No ☐Unknown				
Have any previous babies weighed (tick all that apply):	☐< 2.5 kg ☐ >4.5kg ☐No ☐Unknown		**Have any previous babies had microcephaly**	☐Yes ☐No ☐Unknown	
Have any previous babies had other congenital abnormalities	☐Yes ☐No ☐Unknown		**If yes, specify:**		
Consanguinity	☐Yes ☐No ☐Unknown				
Gestational age		weeks		days	**Estimated date of delivery** (dd/mm/yyyy)	__ / ___ / 20 ___
Estimated date of conception (dd/mm/yyyy)	____ / _____ / 20 ____				
Birth	☐Singleton ☐Twin ☐Triplet ☐Other:				
National or international travel during this pregnancy	☐Yes ☐No ☐Unknown				
If yes, specify all countries or regions visited below					
Country/region visited	Date of visit (dd/mm/yyyy)		Duration of visit (days)		

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2) MATERNAL CHRONIC COMORBIDITIES

Chronic cardiovascular disease[1]	☐Yes ☐No ☐Unknown
Chronic pulmonary disease[2]	☐Yes ☐No ☐Unknown
Blood disorders	☐Yes ☐No ☐Unknown
If yes, please specify:	
Chronic renal/kidney disease[3]	☐Yes ☐No ☐Unknown
Chronic liver disease – moderate or severe[4]	☐Yes ☐No ☐Unknown
Chronic neurological disease[5]	☐Yes ☐No ☐Unknown
If yes, please specify:	
Paralysis existing prior to this pregnancy	☐Yes ☐No ☐Unknown
If yes, please specify body parts affected:	
Type 1 Diabetes	☐Yes ☐No ☐Unknown
Type 2 Diabetes and treated with oral medicine or insulin dependent	☐Yes ☐No ☐Unknown
Other endocrine disease[6]	☐Yes ☐No ☐Unknown
Rheumatologic disease[7]	☐Yes ☐No ☐Unknown
Immunosuppression	☐Yes ☐No ☐Unknown
HIV[8]	☐Yes ☐No ☐Unknown
If yes, on antiretroviral therapy?	☐Yes ☐No ☐Unknown
CD4 cell count	☐ <200 cells/µL ☐200-499 cells/µL ☐ ≥500 cells/µL ☐Unknown
Other immunosuppression?	☐Yes ☐No ☐Unknown
If yes, please specify:	☐Yes ☐No ☐Unknown
Any other chronic comorbidity (please specify):	☐Yes ☐No ☐Unknown

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[1] Includes coronary heart disease, cerebrovascular disease (stroke), hypertension (Diastolic > 100), peripheral artery disease, rheumatic heart disease, congenital heart disease and heart failure. www.who.int/topics/cardiovascular_diseases/en/

[2] Chronic lung diseases that cause limitations in lung airflow (previously referred to as emphysema, chronic bronchitis), diagnosed by spirometry or clinical signs e.g. abnormal shortness of breath and increased forced expiratory time. www.who.int/respiratory/copd/diagnosis/en/

[3] Creatinine >3mg% (265 umol/l), dialysis, transplantation, uremic syndrome

4 Cirrhosis with PHT +/- variceal bleeding

5 Disorders of the nervous system e.g. epilepsy, MS, Parkinson, chronic pain syndromes, chronic brain injuries, ALS etc.

6 Hypopituarism, adrenal insufficiency, recurrent acidosis

7 SLE, polymyositis, polymyalgia rheumatic, mixed connective tissue diseases

8 Laboratory-confirmed HIV-1 or HIV-2 infection (irrespective of the CD4 lymphocyte count/percentage or HIV viral load in blood), or a patient with an AIDS-defining condition.

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3) MEDICATIONS DURING THIS PREGNANCY (prior to onset of current illness episode)

Fever or pain treatment	**Acetaminophen/paracetamol**	☐Yes ☐No ☐Unknown
	NSAID/s	☐Yes ☐No ☐Unknown
	Other/s (specify):	
Anticonvulsants	☐Yes ☐No ☐Unknown **If yes, specify generic name:**	
Drug against nausea during this pregnancy	☐Yes ☐No ☐Unknown **If yes, specify generic name:**	
Prenatal vitamins	☐Yes ☐No ☐Unknown **If yes, specify (e.g folic acid):**	

4) OTHER MEDICATIONS USED DURING THIS PREGNANCY

Medication history Please list **all** other medications taken by the patient during this pregnancy episode, including antibiotics, antivirals and other regular medications, including herbal, and non-licensed remedies. Please list generic names if possible.

Medications or herbal remedies or others including non-licensed	Route of administration
	☐Oral ☐IV ☐other:
	☐Oral ☐IV ☐other:
	☐Oral ☐IV ☐other:
	☐Oral ☐IV ☐other:
	☐Oral ☐IV ☐other:
	☐Oral ☐IV ☐other:
	☐Oral ☐IV ☐other:

5) SMOKING, ALCOHOL, DRUGS AND BLOOD TRANSFUSION

Smoking during this pregnancy	☐Yes ☐No ☐Unknown	**If yes, specify average per day:**	☐ <10 cigarettes per day ☐ ≥10 cigarettes per day
Alcohol consumption during this pregnancy	☐Yes ☐No ☐Unknown	**If yes, specify average alcohol consumption per day Specify type**_____	☐ Less than 1-2 alcoholic drinks[9] per day ☐ 2-5 alcoholic drinks per day ☐ >5 alcoholic drinks per day
Illicit and recreational drug use during this pregnancy	☐Yes ☐No ☐Unknown	**If yes, specify all types of drugs used and route of administration:**	
Has the patient received a blood transfusion?	☐Yes ☐No ☐Unknown	**Specify/estimate date of last blood transfusion and reason for transfusion:**	

[9] A drink is defined as any alcoholic drink for example a glass of wine, a glass of beer, a cocktail

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6) MATERNAL IMMUNISATION HISTORY

Vaccine	Immunised	Date of last dose (dd/mm/yyyy)
Rubella	☐Yes ☐No ☐Unknown	
Measles	☐Yes ☐No ☐Unknown	
Mumps	☐Yes ☐No ☐Unknown	
Acellular pertussis	☐Yes ☐No ☐Unknown	
Varicella	☐Yes ☐No ☐Unknown	
Tetanus	☐Yes ☐No ☐Unknown	
Diphtheria	☐Yes ☐No ☐Unknown	
Polio	☐Yes ☐No ☐Unknown	
Seasonal influenza	☐Yes ☐No ☐Unknown	
Yellow fever	☐Yes ☐No ☐Unknown	
Japanese encephalitis	☐Yes ☐No ☐Unknown	
Tick-born encephalitis	☐Yes ☐No ☐Unknown	
Dengue virus	☐Yes ☐No ☐Unknown	
Any other vaccinations received during this pregnancy (specify):		
Any other vaccinations received during this pregnancy (specify):		

7) DIAGNOSTIC OUTCOME MOTHER

Record final diagnostics outcomes based on laboratory results, clinical picture and case definitions. Choose the appropriate case definition, e.g WHO or national/local case definition and ensure the definition used is clear and shared with all involved in the study.

Pathogen	Diagnosis	Date of onset (dd/mm/yyyy)	Comment
Zika virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	

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Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Toxoplasmosis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Rubella	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Cytomegalovirus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Herpes Simplex virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Syphilis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / ____ / 20 ___	
Other (specify):	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	__ / ____ / 20 ___	
Other (specify):	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	__ / ____ / 20 ___	

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8) FINAL OUTCOME

Outcome	Details
Date of discharge/going home (dd/mm/yyyy)	__ / __ / 20 ____
Maternal outcome at discharge/going home	☐Discharged/sent home without sequelae ☐Discharged with sequelae ☐Deceased
If discharged with sequelae, describe:	
If deceased, specify date of death (dd/mm/yyyy)	__ / ___ / 20 ____
Birth outcome	☐Live birth ☐Antepartum death ☐Intrapartum death ☐Spontaneous abortion ☐Therapeutic abortion
Maternal Zika virus infection	☐Positive ☐Probable ☐Negative ☐Unknown ☐Not tested
Diagnosis confirmed by:	☐Lab. confirmed local hospital laboratory ☐Lab. confirmed by national reference laboratory ☐Lab. confirmed by international reference laboratory ☐Other:_____
Other maternal outcomes, specify all:	

9) CASE REPORT FORM COMPLETED BY

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