ZIKA VIRUS CASE REPORT FORM - MATERNAL ANTENATAL CARE

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 update address 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 - MATERNAL ANTENATAL CARE

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

Name of site/clinic/hospital		
Geoposition	**Latitude** ___._____	**Longitude**__._____
If geoposition not available, complete location below		
City		
Country		

1) ANTENATAL /PRENATAL CARE

Mother's blood group and Rhesus status	☐ A ☐ B ☐ AB ☐ O	☐Rhesus positive ☐Rhesus negative ☐Unknown	
Mother's last menstrual period (dd/mm/yyyy)	__ / ____ / 20 ___	☐Certain ☐Uncertain ☐Unknown	
1st Trimester Ultrasound (<14 weeks' gestation)			
1st Trimester Ultrasound	☐Yes ☐Not done ☐Unknown	**Date of scan** (dd/mm/yyyy)	__ / ___ / 20 ___
Gestational age at time of ultrasound scan	___ weeks ___ days	**Basis of gestational age estimation at time of ultrasound scan**	☐Last menstrual period ☐Ultrasound ☐Assisted reproduction ☐ Other
Is the report and/or images attached?	Report ☐Yes ☐No Images ☐Yes ☐No		
1st Trimester Ultrasound results			
Fetal cardiac activity	☐Detected ☐Not detected	**Crown-rump length (CRL)**	☐ mm
Biparietal diameter (BPD)	☐ mm	**Nuchal translucency**	☐ mm
Down's syndrome screening	☐Low-risk ☐High-risk ☐Not Done ☐Unknown	**If high-risk, please specify tests used and results:**	
Anomalies identified	☐Yes ☐No ☐Unknown		
If anomalies/ abnormalities were detected; please tick all that apply:	○Holoprosencephaly ○Anencephaly ○Encephalocoele ○Spina bifida ○Exomphalos ○Gastroschisis ○Megacystis ○Cardiac abnormality	○Limb abnormality, (specify): ○Skeletal abnormality, (specify): ○Other, please specify:	

ZIKA VIRUS CASE REPORT FORM - MATERNAL ANTENATAL CARE

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

Any other significant findings	☐Yes ☐No	**If yes, please specify/describe:**

2nd Trimester			
Fetal movements	☐Normal ☐Reduced ☐ Increased ☐Unknown		
2nd Trimester Ultrasound	☐Yes ☐Not done ☐Unknown	**Date of scan** (dd/mm/yyyy)	__ / ___ / 20 ___
Gestational age at time of ultrasound scan	___ weeks ___ days	**Basis of gestational age estimation at time of ultrasound scan**	☐Last menstrual period ☐ Ultrasound ☐Assisted reproduction ☐Other
Is the report and/or images attached?	Report ☐Yes ☐No Images ☐Yes ☐No		

2nd Trimester Ultrasound results (14 - 24 weeks' gestation)			
Head circumference (HC)	☐ mm	**Biparietal diameter (BPD)**	☐ mm
Abdominal circumference (AC)	☐ mm	**How was BPD measured:** Outer-to-outer Outer-to-inner	 ☐ ☐
Trans cerebellar diameter (TCD)	☐ mm	**Femur length (FL)**	☐ mm
Were any cerebral anomalies detected (e.g. calcification or ventriculomegaly)?	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	
Were any cerebellar anomalies detected (e.g reduced size or calcification)?	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	

If other anomalies were detected, please tick all that apply:	Head ☐Yes ☐No Brain ☐Yes ☐No Face ☐Yes ☐No Neck ☐Yes ☐No Spine ☐Yes ☐No Heart ☐Yes ☐No Anterior abdominal wall ☐Yes ☐No Gastro-intestinal ☐Yes ☐No Bladder ☐Yes ☐No Chromosomal abnormality (after amniocentesis or CVS) ☐Yes ☐No	Limbs ☐Yes ☐No Lungs/Pleura ☐Yes ☐No Kidneys ☐Yes ☐No Genitalia ☐Yes ☐No Two vessel cord ☐Yes ☐No Other ☐Yes ☐No
Detailed information about anomalies		

ZIKA VIRUS CASE REPORT FORM - MATERNAL ANTENATAL CARE

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

Amniotic volume	☐Normal ☐Increased ☐Polyhydramnios ☐Reduced ☐Oligohydramnios ☐Anhydramnios ☐Unknown

3rd Trimester Ultrasound (>24 weeks' gestation)

Fetal movements	☐Normal ☐Reduced ☐ Increased ☐Unknown		
3rd Trimester Ultrasound	☐Yes ☐Not done ☐Unknown	**Date of scan** (dd/mm/yyyy)	__ / ___ / 20 ___
Gestational age at time of ultrasound scan	___ weeks ___ days	**Basis of gestational age estimation at time of ultrasound scan**	☐Last menstrual period ☐ Ultrasound ☐Assisted reproduction ☐Other:
Is the report and/or images attached?	Report ☐Yes ☐No Images ☐Yes ☐No		

3rd Trimester Ultrasound results

Head circumference (HC)	☐ mm	**Biparietal diameter (BPD)**	☐ mm
Abdominal circumference (AC)	☐ mm	**How was BPD measured:** Outer-to-outer Outer-to-inner	 ☐ ☐
Transcerebellar diameter (TCD)	☐ mm	**Femur length (FL)**	☐ mm
Were any cerebral anomalies detected (e.g. calcification or ventriculomegaly)?	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	
Were any cerebellar anomalies detected (e.g reduced size or calcification)?	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	

If other anomalies were detected, please tick all that apply:	Head ☐Yes ☐No Brain ☐Yes ☐No Face ☐Yes ☐No Neck ☐Yes ☐No Spine ☐Yes ☐No Heart ☐Yes ☐No Anterior abdominal wall ☐Yes ☐No Gastro-intestinal ☐Yes ☐No	Bladder ☐ Yes ☐No Limbs ☐Yes ☐No Lungs/Pleura ☐Yes ☐No Kidneys ☐Yes ☐No Genitalia ☐Yes ☐No Chromosomal abnormality (after amniocentesis or CVS) ☐Yes ☐No Two vessel cord ☐Yes ☐No Other ☐Yes ☐No
Detailed information about anomalies		

ZIKA VIRUS CASE REPORT FORM - MATERNAL ANTENATAL CARE

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

Amniotic volume	☐Normal ☐Increased ☐Polyhydramnios ☐Reduced ☐Oligohydramnios ☐Anhydramnios ☐Unknown		
Placenta praevia	☐Yes ☐No ☐Unknown		
Other placental abnormalities	☐Yes ☐No ☐Unknown	**If yes, please specify:**	
Umbilical artery Doppler	☐Positive end diastolic flow ☐ Absent end diastolic flow ☐Reverse end diastolic flow ☐Unknown		Resistance index (RI) ☐ Pulsatility index (PI) ☐

2) OTHER TESTS

Amniocentesis **Date of amniocentesis:** (dd/mm/yyyy) **__ / __ / 20 __**	☐Normal ☐Abnormal ☐Not Done ☐Unknown	**If abnormal, please specify significant findings:**	
Other intrauterine test/s: **Date of test:** **__ / __ / 20 __**	☐Yes ☐No ☐Unknown	**If yes, please specify tests and significant findings:**	
Other intrauterine test/s: **Date of test:** **__ / __ / 20 __**	☐Yes ☐No ☐Unknown	**If yes, please specify tests and significant findings:**	
Other test/s: **Date of test:** **__ / __ / 20 __**	☐Yes ☐No ☐Unknown	**If yes, please specify tests and significant findings:**	

ZIKA VIRUS CASE REPORT FORM - MATERNAL ANTENATAL CARE

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

3) MATERNAL COMPLICATIONS IN PREGNANCY Record complications with onset during pregnancy

CLINICAL CONDITIONS **During the pregnancy was she diagnosed with, or treated for, any of the following conditions:**			
Diabetes, thyroid disease or other endocrinological condition	☐Yes ☐No	Respiratory tract infection needing antibiotic/antiviral treatment	☐Yes ☐No
Any malignancy/cancer (including leukaemia or lymphoma)	☐Yes ☐No	Any other infection needing antibiotic/ antiviral treatment	☐Yes ☐No
Cardiac disease	☐Yes ☐No	Group B streptococcus carrier	☐Yes ☐No
Epilepsy	☐Yes ☐No	HIV or AIDS	☐Yes ☐No
Mental illness, e.g. clinical depression	☐Yes ☐No	Genital tract infection or STD	☐Yes ☐No
		Cholestasis	☐Yes ☐No
Pyelonephritis or kidney disease	☐Yes ☐No	Any other medical/surgical condition needing treatment/referral	☐Yes ☐No
Lower urinary tract infection needing antibiotic treatment	☐Yes ☐No	Any accident or maternal trauma needing hospital admission or referral to a higher level of care	☐Yes ☐No

PREGNANCY-RELATED CONDITIONS **During the pregnancy was she diagnosed with, or treated for, any of the following conditions:**			
Severe vomiting needing hospitalisation	☐Yes ☐No	Fetal anaemia	☐Yes ☐No
Gestational diabetes	☐Yes ☐No	Fetal distress (abnormal FHR or BPP)	☐Yes ☐No
Vaginal bleeding before 14 weeks	☐Yes ☐No	Suspected impaired fetal growth	☐Yes ☐No
Vaginal bleeding at 14-24 weeks	☐Yes ☐No	Oligohydramnios	☐Yes ☐No
Vaginal bleeding after 24 weeks	☐Yes ☐No	Polyhydramnios	☐Yes ☐No
Pregnancy-induced hypertension (BP>140/90, no proteinuria)	☐Yes ☐No	Condition needing amniocentesis or fetal blood sampling (FBS)	☐Yes ☐No
Pre-eclampsia (BP>140/90 and proteinuria)	☐Yes ☐No	If yes, specify: _____	
		Abruptio placentae	☐Yes ☐No
Severe pre-eclampsia/Eclampsia/HELLP	☐Yes ☐No	Clinical chorioamnionitis	☐Yes ☐No
Rhesus disease or anti-Kell antibodies	☐Yes ☐No	Other (specify):_____	☐Yes ☐No
Preterm labour	☐Yes ☐No		

Lowest haemoglobin level	**< 14 weeks**	**14-24 weeks**	**>24 weeks**
	☐☐.☐ g/dl	☐☐.☐ g/dl	☐☐.☐ g/dl
OR lowest haematocrit	☐☐.☐ %	☐☐.☐ %	☐☐.☐ %

4) CASE REPORT FORM COMPLETED BY

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