ZIKA VIRUS CASE REPORT FORM – NEONATE BASELINE AND OUTCOME

Neonate identification code: _____ **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 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 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*.

ZIKA VIRUS CASE REPORT FORM – NEONATE BASELINE AND OUTCOME

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

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: ____: ___hrs

Signature of the person taking consent: _____

Name of the person taking consent: _____

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

ZIKA VIRUS CASE REPORT FORM – NEONATE BASELINE AND OUTCOME

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

1) NEONATE DEMOGRAPHICS

Sex	☐Male ☐Female ☐Uncertain
Date of birth (dd/mm/yyyy)	____ / ____ / 20 ____
Gestational age at birth	____ weeks ____ days
Basis of gestational age estimation at birth	☐Last menstrual period ☐Ultrasound ☐Assisted reproduction ☐Other (specify):
Birth number	☐Singleton ☐Twin I ☐Twin II ☐Triplet I ☐Triplet II ☐Triplet III ☐Other: _____
Ethnicity of baby (as per national guidelines)	
Fetal presentation at delivery	☐Cephalic ☐Breech ☐Other (specify):

2) NEONATE MEASUREMENTS AT BIRTH

Apgar scores	☐ 1 min		☐ 5 min		☐ 10 min	
Birth weight (<12 hrs after delivery)	☐	gram	☐	pounds	☐	ounces
Crown-to-heel length	☐	cm	☐	inches	☐ unknown	
Head circumference (occipito-frontal)	☐	cm	☐	inches	☐ unknown	
Mother's head circumference	☐	cm	☐	inches	☐ unknown	
Father's head circumference	☐	cm	☐	inches	☐ unknown	

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

3) BIRTH ABNORMALITIES

Please complete this section in full even if no abnormalities were present

Fontanelle present	**Anterior:** ☐Yes ☐No ☐Unknown	**Posterior:** ☐Yes ☐No ☐Unknown	
Cephalohaematoma	☐Yes ☐No ☐Unknown	**Subgaleal haemorrhage**	☐Yes ☐No ☐Unknown
Craniosynostosis	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	
Omphalocele	☐Yes ☐No ☐Unknown	**Ear abnormalities**	☐Anotia/microtia ☐Other (describe): _____ ☐No ☐Unknown
Cleft lip/cleft palate	☐Yes ☐No ☐Unknown	**Gastroschisis**	☐Yes ☐No ☐Unknown
Down's syndrome	☐Yes ☐No ☐Unknown	**Neural tube defects, e.g. spina bifida, meningocele**	☐Yes ☐No ☐Unknown
Hand abnormalities	☐Clinodacytly ☐Missing digits ☐Other (specify):_____ _____ ☐No ☐Unknown	**Feet abnormalities**	☐Wide spaced toes ☐Other(specify):_____ _____ ☐No ☐Unknown
Upper and lower limb reduction defects	☐Yes ☐No ☐Unknown	**If yes, specify/describe which limb/s:**	
Eye abnormalities	☐**Yes** ☐No ☐Unknown	**If yes, describe:**	
Facial dysmorphism	☐Yes ☐**No** ☐Unknown	**If yes, please describe:**	
Any other significant abnormalities present	☐Yes ☐No ☐Unknown	**If yes, please describe all:**	
Known familial genetic disorders	☐Yes ☐No ☐Unknown	**If yes, please specify:**	
Syndromic abnormalities identified by Physician	☐Yes ☐No ☐Unknown	**If yes, please specify:**	

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

4) OTHER TESTS AND EXAMINATIONS

Test	Result	If abnormal, please describe abnormality:	
Fundoscopy	☐Normal ☐Abnormal ☐Not Done		
Red reflex or chorioretinitis	☐Present ☐Absent ☐Not Done		
Cataract	☐Normal ☐Abnormal ☐Not Done		
Hearing test, please specify test used:	☐Normal ☐Abnormal ☐Not Done		
Congenital heart defects	☐Yes ☐No ☐Unknown	**If yes, please specify:**	
Newborn blood screening	**Hypothyroidism** ☐Negative ☐Positive ☐Not Done	**Phenylketonuria** ☐Negative ☐Positive ☐Not Done	**Other (specify):** ☐Negative ☐Positive
Any other significant findings	☐Yes ☐No ☐Unknown	**If yes, please specify:**	

ZIKA VIRUS CASE REPORT FORM – NEONATE BASELINE AND OUTCOME

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

5) BASELINE OBSERVATIONS DAY 0 (≤ 24 hours post-delivery)

Date (dd/mm/yyyy)		__ __ / __ __ / 20 __ __	
Maximum temperature		_____°C or _____ Fahrenheit ☐Oral ☐Tympanic ☐Rectal ☐Axillary ☐Other (specify):	
Respiratory rate			breaths/minute
Heart rate			beats/minute
Systolic blood pressure			mmHg
Diastolic blood pressure			mmHg
Peripheral O_2 saturation (SpO_2)			%
Cardiovascular system	☐Normal ☐Abnormal ☐Unknown	☐Murmur ☐Other (specify) :	
Respiratory system	☐Normal ☐Abnormal ☐Unknown	If abnormal, describe:	
Gastrointestinal system	☐Normal ☐Abnormal ☐Unknown	☐Jaundice ☐Abdominal tenderness ☐Hepatomegaly ☐Splenomegaly ☐Other (specify):	
Type of cry	☐Strong normal cry ☐Weak, high-pitched or continuous cry ☐Not crying ☐Other:		
Tonic neck reflex	☐Present ☐Absent ☐Not Done	**Moro reflex**	☐Present ☐Absent ☐Not Done
Rooting reflex	☐Present ☐Absent ☐Not Done	**Sucking reflex**	☐Present ☐Absent ☐Not Done
Grasp reflex	☐Present ☐Absent ☐Not Done	**Babinski reflex**	☐Present ☐Absent ☐Not Done
Seizure(s) (focal or general)	☐Yes ☐No ☐Unknown	**If yes, describe:**	
Paralysis	☐Yes ☐No ☐Unknown	**If yes, describe:**	
Hypotonia (floppiness)	☐Yes ☐No ☐Unknown		
Stiffness or spasticity or increased tone of limbs	☐Yes ☐No ☐Unknown	**If yes, describe:**	
Contractures	☐Yes ☐No ☐Unknown	**If yes, describe:**	
Bulging fontanelle	☐Yes ☐No ☐Unknown		
Other neurological signs	☐Yes ☐No ☐Unknown	**If yes, describe:**	
Other abnormal movements e.g writhing movements	☐Yes ☐No ☐Unknown	**If yes, describe:**	
Oedema	☐Yes ☐No ☐Unknown	**If yes, describe affected parts:**	
Rash	☐Yes ☐No ☐Unknown	**If yes, date of rash onset** (dd/mm/yyyy)	__ __ / __ __ / 20 __ __

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

If yes, please describe type of rash		**Body distribution of rash**	
Other significant symptoms/observations	☐Yes ☐No ☐Unknown	**If yes, please describe all:**	

6) IMAGING (if available)

If abnormal, please describe abnormality and enclose images if possible.

Neuroimaging	**Results**	**If abnormal, please summarise key results from report:**	**Images attached**	**Report attached**
Cranial ultrasound scan	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No

7) MEDICATIONS OR SUPPORTIVE CARE TO NEONATE POST-DELIVERY

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

Type of medication	**Name of medication** (generic name)	**Dose and frequency** (eg. 40mg four times daily)	**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

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

8) LABOUR AND DELIVERY

Onset of labour (tick one box only) ☐Spontaneous ☐Induced ☐No labour	**Prelabour premature rupture of membranes (PPROM)** ☐Yes ☐No	**Place of delivery** ☐Home ☐Health facility
Mode of delivery	☐Vaginal spontaneous ☐Vaginal assisted (e.g. forceps , vacuum) ☐Caesarean section ☐Assisted breech or breech extraction	

If labour was induced, or Caesarean section performed, please tick all that apply:

Vaginal bleeding	☐Yes ☐No	Rhesus disease or anti-Kell antibodies	☐Yes ☐No
Placenta praevia	☐Yes ☐No	Intrahepatic cholestasis of pregnancy	☐Yes ☐No
Fetal death	☐Yes ☐No	Post-term (>42 weeks' gestation)	☐Yes ☐No
Pregnancy-induced hypertension	☐Yes ☐No	HIV or AIDS	☐Yes ☐No
Pre-eclampsia	☐Yes ☐No	Genital tract infection or STD	☐Yes ☐No
Severe pre-eclampsia/eclampsia/HELLP	☐Yes ☐No	Infection requiring antibiotics/antivirals	☐Yes ☐No
Breech presentation	☐Yes ☐No	Accident/maternal trauma	☐Yes ☐No
Fetal distress (abnormal FHR or BPP)	☐Yes ☐No	Pregnancy termination	☐Yes ☐No
Reduced fetal movement	☐Yes ☐No	Previous Caesarean section	☐Yes ☐No
Failure to progress	☐Yes ☐No	Worsening of pre-existing condition	☐Yes ☐No
Cephalo-pelvic disproportion	☐Yes ☐No	If yes, specify:_____	
PPROM	☐Yes ☐No	Any other maternal reason	☐Yes ☐No
Uterine rupture	☐Yes ☐No	If yes, specify:_____	
Abruptio placentae	☐Yes ☐No	Any other fetal reason	☐Yes ☐No
Suspected IUGR	☐Yes ☐No	If yes, specify:_____	

If yes to any of the above, specify:

Placental weight	_____	☐grams ☐Other units (specify):	
Placental calcifications	☐Yes ☐No ☐Unknown		
Other placental abnormalities	☐Yes ☐No ☐Unknown	**If yes, please specify:**	

Intrapartum Complications

Haemorrhage	☐Yes ☐No ☐Unknown	**If yes, specify source of bleeding:**	
Chorioamnionitis	☐Yes ☐No ☐Unknown	**If yes, specify positive microbiology result:**	
Fetal scalp blood sample	☐Yes ☐No ☐Unknown	**If yes, record results:**	
Fetal hypoxia	☐Yes ☐No ☐Unknown	**If yes, specify tests used:**	
Cardiotocography (CTG) abnormalities	☐Yes ☐No ☐Unknown	**If yes, specify:**	
Other complication(s)	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	

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

Postpartum Complications				
Postpartum complications (including postpartum haemorrhage)	☐Yes ☐No ☐Unknown	**If yes, please specify:**		
Neonatal hypoglycaemia	☐Yes ☐No ☐Unknown	**Please specify glucose value and unit:**	☐	☐ mg/dL ☐ mmol/L

9) NEONATE HOSPITAL ADMISSION

Was the neonate admitted to hospital		☐Yes ☐No ☐Unknown	
If yes, state the name of the hospital			
City			
Reason for admission			
Date of admission (dd/mm/yyyy)	____ / ____ / 20 ____	**Length of stay** (days)	_____ days ☐Unknown
Was the neonate admitted to intensive care (ITU/PICU/NICU/PHDU)		☐Yes ☐No ☐Unknown	
If yes, please also complete the Zika virus Case Report Form (CRF) – Neonate Intensive Care module			

10) DIAGNOSTICS OUTCOMES NEONATE

Record the final diagnosis based on laboratory tests performed, clinical picture and case definitions when available. 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. Please complete the Zika virus CRF Neonate Laboratory Results module.

Pathogen	Diagnosis	Comment
Zika virus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Dengue virus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Yellow fever virus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
West Nile virus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	

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

Chikungunya virus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Toxoplasmosis	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Rubella	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Cytomegalovirus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Herpes Simplex virus	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Other (specify):	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	
Other (specify):	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed congenital infection ☐Probable congenital infection ☐Negative ☐Not tested ☐Unknown	

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

11) OUTCOME AT DISCHARGE – NEONATE complete at discharge or death

DATE OF DISCHARGE (dd/mm/yyyy**):** __ / __ / 20 ____

Neonate's status at discharge:

☐ Discharged with no abnormalities
☐ Discharged with neurological sequelae (e.g. seizures, spasticity, hypotonia, abnormal movements)
☐ Discharged with birth abnormality
☐ Antepartum death
☐ Intrapartum death

Microcephaly (as defined in the study inclusion Criteria): ☐Yes ☐No ☐Unknown

If discharged with neurological sequelae, please specify:

_____

_____

If discharged with other abnormality specify all:

_____ _____

_____ _____

_____ _____

DIAGNOSTICS OUTCOME

Zika virus ☐Positive ☐Probable ☐Negative ☐Unknown ☐Not tested

Diagnosis confirmed by: ○Lab. confirmed locally ○Lab. confirmed by regional reference laboratory
○Other:_____

Case definition/certainty of diagnosis (in line with national definitions):

☐Possible ☐Probable ☐Confirmed

Comment on case definition:_____

If deceased please specify date of death (dd/mm/yyyy**):** **__ / __ / 20 ___**
Was autopsy performed: ☐**Yes** ☐**No** ☐**Unknown** **Date of autopsy: __ / __ / 20 ___**

Any other outcome, describe all:_____

_____

_____

12) CASE REPORT FORM COMPLETED BY

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