ZIKA VIRUS CASE REPORT FORMS – MATERNAL ANTENATAL CARE – (MAC)

Mother's Identification Code : _____ Neonate's Identification Code : _____

Introduction

This standardized Case Report Form (CRF) is the result of an ongoing effort between the World Health Organization (WHO), The Pan-American Health Organization (PAHO), Institute Pasteur (IP), and the networks of ISARIC, CONSISE PREPARE and REACTing to generate standardized clinical and epidemiological research tools.

DESIGN OF THIS CASE REPORT FORM (CRF)

There are two sets of Case Report Form (CRF) to be used - Neonate and Maternal. The CRFs are to be used in combination for prospective 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 **Maternal Baseline and Outcome (MBO)** and **Neonate Baseline and Outcome (NBO)** CRFs, follow by **Maternal Laboratory Results (MLR)** and **Neonate Laboratory Results (NLR)** CRFs for all neonates post-delivery. If the mother and/or neonate is admitted to an Intensive Care Unit or Pediatric Intensive Care Unit, complete **Maternal Intensive Care (MIC)**, and/or **Neonate Intensive Care (NIC)** as well.

For pregnant women presenting with acute symptoms, complete **Maternal Acute Symptoms (MAS)**, and for all studies complete **Maternal Antenatal Care (MAC).**

Complete the outcomes sections in CRFs **MBO** and **NBO** 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 study and the informed consent form has been completed and signed.
- The study ID codes have been 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 identifiable information is recorded on the CRFs.
- Patients' hospital ID and contact details are 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 which 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 **Maternal and Neonatal 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 CRFs are designed to collect data obtained through patient examination, through parent/guardian/representative (for neonates) 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 indicate 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 standardized 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.

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- Please keep all of the sheets for each study subject together e.g. with a staple or in a folder that is unique to the patient.
- Please contact us 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 standardized 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 standardized 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 systems.*

1. Name of site/clinic/hospital	
2. Geoposition	**Latitude: ____. _____ Longitude____. _____**
If geoposition not available:	
3. City/town/village	
4. Country:	

1) ANTENATAL /PRENATAL CARE

5. Mother's blood group and Rhesus status	☐ A ☐ B ☐ AB ☐ O	☐Rhesus positive ☐Rhesus negative ☐Unknown	
6. Mother's last menstrual period (dd/mm/yyyy)	__ / ____ / 20 ___	☐Certain ☐Uncertain ☐Unknown	
1st Trimester Ultrasound (<14 weeks' gestation)			
7. 1st Trimester Ultrasound	☐Yes ☐Not done ☐Unknown	**8. Date of scan** (dd/mm/yyyy)	__ / ___ / 20 ___
9. Gestational age at time of ultrasound scan	___ weeks ___ days ☐ Unknown	**10. Basis of gestational age estimation at time of ultrasound scan**	☐Last menstrual period ☐Ultrasound ☐Assisted reproduction ☐ Other(specify):
11. Is the report and/or images attached?	Report ☐Yes ☐No Images ☐Yes ☐No		
1st Trimester Ultrasound results			
12. Fetal cardiac activity	☐Detected ☐Not detected ☐Not investigated	**13. Crown-rump length (CRL)**	**_____mm** ☐ Not Done ☐Unknown
14. Biparietal diameter (BPD)	**_____mm** ☐ Not Done ☐Unknown	**15. Nuchal translucency**	**_____mm** ☐ Not Done ☐Unknown
16. Down's syndrome screening	☐Low-risk ☐High-risk ☐Not Done ☐Unknown	**17. If high-risk, please specify:**	**Tests** **Results**
18. Anomalies identified	☐Yes ☐No ☐Unknown		

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If anomalies/ abnormalities were detected; please tick all that apply:	○ Holoprosencephaly ○ Anencephaly ○ Encephalocele ○ Spina bifida ○ Exomphalos ○ Gastroschisis ○ Megacystis ○ Cardiac abnormality	Limb abnormality: ☐Yes ☐No (if yes, specify):_____ Skeletal abnormality: ☐Yes ☐No (if yes, specify):_____ Other: ☐Yes ☐No (if yes, specify):_____
19. Any other significant findings	☐Yes ☐No	**If yes, please specify/describe:**

2nd Trimester Ultrasound (14-24 weeks' gestation)			
20. Fetal movements	☐Normal ☐Reduced ☐Increased ☐Unknown		
21. 2rd Trimester Ultrasound	☐Yes ☐Not done ☐Unknown	**22. Date of scan** (dd/mm/yyyy)	__ / ___ / 20 ___
23. Gestational age at time of ultrasound scan	___ weeks ___ days ☐Unknown	**24. Basis of gestational age estimation at time of ultrasound scan**	☐Last menstrual period ☐ Ultrasound ☐Assisted reproduction ☐Symphyseal-fundal height ☐Other (specify):
25. Is the report and/or images attached?	Report ☐Yes ☐No Images ☐Yes ☐No		
2nd Trimester Ultrasound results			
26. Head circumference (HC)	**_____mm** ☐ Not Done ☐Unknown	**27. Biparietal diameter (BPD)**	**_____mm** ☐ Not Done ☐Unknown
28. How was BPD measured:	☐ Outer-to-outer ☐ Outer-to-inner ☐ Unknown	**29. Abdominal circumference (AC)**	**_____mm** ☐ Not Done ☐Unknown
30. Trans cerebellar diameter (TCD)	**_____mm** ☐ Not Done ☐Unknown	**31. Femur length (FL)**	**_____mm** ☐ Not Done ☐Unknown
32. Were any cerebral anomalies detected (e.g. calcification or ventriculomegaly)?	☐ Yes ☐ No ☐ Unknown	**If yes, specify/describe:**	
33. Were any cerebellar anomalies detected (e.g. reduced size or calcification)**?**	☐ Yes ☐ No ☐ Unknown	**If yes, specify/describe:**	

34. If other anomalies were detected, please tick all that apply:	Head	○ Yes ○ No		Bladder	○ Yes ○ No
	Brain	○ Yes ○ No		Chromosomal abnormality (after amniocentesis/CVS)	○ Yes ○ No
	Face	○ Yes ○ No			
	Neck	○ Yes ○ No		Limbs	○ Yes ○ No
	Spine	○ Yes ○ No		Lungs/Pleura	○ Yes ○ No

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	Heart ○ Yes ○ No Anterior abdominal wall ○ Yes ○ No Gastro-intestinal ○ Yes ○ No	Kidneys ○Yes ○No Genitalia ○Yes ○No Two vessel cord ○Yes ○No Other ☐Yes ☐No
35. Amniotic volume	☐Normal ☐Polyhydramnios ☐Oligohydramnios ☐Anhydramnios ☐Unknown	

3rd Trimester Ultrasound (>24 weeks' gestation)			
36. Fetal movements	☐Normal ☐Reduced ☐Increased ☐Unknown		
37. 3rd Trimester Ultrasound	☐Yes ☐Not done ☐Unknown	**38. Date of scan** (dd/mm/yyyy)	__ / ___ / 20 ___
39. Gestational age at time of ultrasound scan	___ weeks ___ days ☐ Unknown	**40. Basis of gestational age estimation at time of ultrasound scan**	☐Last menstrual period ☐ Ultrasound ☐Assisted reproduction ☐Symphyseal-fundal height ☐Other (specify):_____
41. Is the report and/or images attached?	Report ☐Yes ☐No Images ☐Yes ☐No		
3rd Trimester Ultrasound results			
42. Head circumference (HC)	**_____mm** ☐ Not Done ☐Unknown	**43. Biparietal diameter (BPD)**	**_____mm** ☐ Not Done ☐Unknown
44. How was BPD measured:	☐ Outer-to-outer ☐ Outer-to-inner ☐ Unknown	**45. Abdominal circumference (AC)**	**_____mm** ☐ Not Done ☐Unknown
46. Trans cerebellar diameter (TCD)	**_____mm** ☐ Not Done ☐Unknown	**47. Femur length (FL)**	**_____mm** ☐ Not Done ☐Unknown
48. Were any cerebral anomalies detected (e.g. calcification or ventriculomegaly)?	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	
49. Were any cerebellar anomalies detected (e.g. reduced size or calcification)?	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	

50. 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/CVS) ○Yes ○No Limbs ○Yes ○No Lungs/Pleura ○Yes ○No Kidneys ○Yes ○No Genitalia ○Yes ○No Two vessel cord ○Yes ○No Other ☐Yes ☐No

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Detailed information about anomalies			
51. Amniotic volume	☐Normal ☐Polyhydramnios ☐Oligohydramnios ☐Anhydramnios ☐Unknown		
52. Placenta previa	☐Yes ☐No ☐Unknown		
53. Other placental abnormalities	☐Yes ☐No ☐Unknown	**If yes, please specify:**	
54. 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

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

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:			
57. Diabetes, thyroid disease or other endocrine condition	☐Yes ☐No ☐Unknown	**58. Any malignancy/cancer (including leukemia or lymphoma)**	☐Yes ☐No ☐Unknown
59. Cardiac disease	☐Yes ☐No ☐Unknown	**60. Epilepsy**	☐Yes ☐No ☐Unknown
61. Mental illness, e.g. clinical depression	☐Yes ☐No ☐Unknown	**62. Pyelonephritis or kidney disease**	☐Yes ☐No ☐Unknown
63. Lower urinary tract infection needing antibiotic treatment	☐Yes ☐No ☐Unknown	**64. Respiratory tract infection needing antibiotic/antiviral treatment**	☐Yes ☐No ☐Unknown

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65. Group B streptococcus carrier	☐Yes ☐No ☐Unknown	**66. HIV or AIDS**	☐Yes ☐No ☐Unknown
67. Genital tract infection or STD	☐Yes ☐No ☐Unknown	**68. Any other infection needing antibiotic/ antiviral treatment**	☐Yes ☐No ☐Unknown
69. Cholestasis	☐Yes ☐No ☐Unknown	**70. Any accident or maternal trauma needing hospital admission or referral to a higher level of care**	☐Yes ☐No ☐Unknown
71. Any other medical/surgical condition needing treatment/referral	☐Yes ☐No ☐Unknown		
PREGNANCY-RELATED CONDITIONS **During the pregnancy was she diagnosed with, or treated for, any of the following conditions:**			
72. Severe vomiting needing hospitalization	☐Yes ☐No ☐Unknown	**73. Gestational diabetes**	☐Yes ☐No ☐Unknown
74. Vaginal bleeding before 14 weeks	☐Yes ☐No ☐Unknown	**75. Vaginal bleeding at 14-24 weeks**	☐Yes ☐No ☐Unknown
76. Vaginal bleeding after 24 weeks	☐Yes ☐No ☐Unknown	**77. Pregnancy-induced hypertension (BP>140/90 mmHg, no proteinuria)**	☐Yes ☐No ☐Unknown
78. Pre-eclampsia (BP>140/90 mmHg and proteinuria)	☐Yes ☐No ☐Unknown	**79. Severe pre-eclampsia / Eclampsia /HELLP**	☐Yes ☐No ☐Unknown
80. Rhesus disease or anti-Kell antibodies	☐Yes ☐No ☐Unknown	**81. Preterm labor**	☐Yes ☐No ☐Unknown
82. Fetal anemia	☐Yes ☐No ☐Unknown	**83. Fetal distress (abnormal FHR or BPP)**	☐Yes ☐No ☐Unknown
84. Suspected impaired fetal growth	☐Yes ☐No ☐Unknown	**85. Oligohydramnios**	☐Yes ☐No ☐Unknown
86. Polyhydramnios	☐Yes ☐No ☐Unknown	**87. Clinical chorioamnionitis**	☐Yes ☐No ☐Unknown
88. Condition needing amniocentesis or fetal blood sampling (FBS) **If yes, specify:** _____	☐Yes ☐No ☐Unknown	**89. Abruptio placentae**	☐Yes ☐No ☐Unknown
90. Other (specify):	☐Yes ☐No		

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	< 14 weeks	**14-24 weeks**	**>24 weeks**
91. Lowest hemoglobin level	____.__ g/dl	____.__ g/dl	____.__ g/dl
OR **92. Lowest hematocrit level**	_____%	_____%	_____%

4) CASE REPORT FORM COMPLETED BY

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