ZIKA VIRUS CASE REPORT FORMS – MATERNAL BASELINE AND OUTCOME – (MBO)

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.
- 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.

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- 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.*

INCLUSION CRITERIA

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

CONSENT

Ensure informed consent.

Date and time of consent (dd/mm/yyyy): __ __ / __ __ / _20_ __ __ Time: __ __: __ __(hours:min)
Name and role of the person taking consent : _____
Signature of person taking consent: _____

1. Name of site/clinic/hospital		
2. Geoposition	**Latitude** ___ . _____	**Longitude** ___ . _____
If geoposition not available, state location below		
Name of the site/clinic/hospital		
3. City/town /village:		
4. Country (& region/district):		
5. Acute symptoms in pregnant mother	☐Yes ☐No If yes, please also complete the **Maternal Acute Symptoms CRF**	

1) MATERNAL DEMOGRAPHICS

6. Date of birth (dd/mm/yyyy)	___ / ____ / _____			
7. Ethnicity (according to national guidelines):				
8. Home city/town /village during pregnancy, state all during this pregnancy				
City/town/village		**Date from** (mm/yyyy)	**To** (mm/yyyy)	
9. Occupation				
10. Height		☐cm ☐feet/inches		
11. Weight (prior to pregnancy, specify or estimate):	☐kg ☐pounds/ounces	**12. Current weight**	☐kg ☐pounds/ounces	
13. Familial genetic conditions on maternal or paternal side	☐Yes ☐No ☐Unknown	**If yes, specify:**		

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14. Number of previous pregnancies (excluding present pregnancy):		**15. Number of previous births after 22 weeks' gestation:**	
16. Have any previous babies been (tick all that apply)	○ Preterm (<37 weeks' gestation) ○ Stillborn or perinatal deaths ☐No ☐Unknown		
17. Have any previous babies weighed (tick all that apply)**:**	○ < 2.5 kg ○ >4.5kg ☐No ☐Unknown	**18. Have any previous babies had microcephaly**	☐Yes ☐No ☐ Unknown
19. Have any previous babies had other congenital abnormalities	☐Yes ☐No ☐Unknown	**If yes, specify:**	
20. Consanguinity	☐Yes ☐No ☐Unknown		
21. If not yet delivered, what is the current gestational age	Weeks _____ Days _____	**22. If not yet delivered, what is the estimated date of delivery** (dd/mm/yyyy)	__ / ___ / 20 ___
23. Estimated date of conception (dd/mm/yyyy)	____ / _____ / 20 ____		
24. Birth number	☐Singleton ☐Twin ☐Triplet ☐Other, please detail:		
25. National or international travel during this pregnancy	☐Yes ☐No ☐Unknown		

If yes, specify all countries or regions visited below

Country/region visited	Approximate first and last date (dd/mm/yyyy)	Duration of visit (days)	Includes overnight stay
	___/___/_____ **to** ___/___/_____		☐ Yes ☐ No
	___/___/_____ **to** ___/___/_____		☐ Yes ☐ No
	___/___/_____ **to** ___/___/_____		☐ Yes ☐ No
	___/___/_____ **to** ___/___/_____		☐ Yes ☐ No
	___/___/_____ **to** ___/___/_____		☐ Yes ☐ No

Note: If further demographic or epidemiology information is required please use a complementary ZIKV CRF Demographics and Epidemiology

2) MATERNAL CHRONIC COMORBIDITIES / PAST MEDICAL HISTORY

26. Chronic cardiovascular disease[1]	☐Yes ☐No ☐Unknown
27. Chronic pulmonary disease[2]	☐Yes ☐No ☐Unknown
28. Blood disorders	☐Yes ☐No ☐Unknown

[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/

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If yes, specify:	
29. Chronic renal/kidney disease[3]	☐Yes ☐No ☐Unknown
30. Chronic liver disease – moderate or severe[4]	☐Yes ☐No ☐Unknown
31. Chronic neurological disease[5]	☐Yes ☐No ☐Unknown
If yes, specify:	
32. Paralysis (existing prior to this pregnancy)	☐Yes ☐No ☐Unknown
If yes, specify body parts affected:	
33. Type 1 Diabetes	☐Yes ☐No ☐Unknown
34. Type 2 Diabetes and treated with oral medicine or insulin dependent	☐Yes ☐No ☐Unknown
35. Other endocrine disease[6]	☐Yes ☐No ☐Unknown
If yes, specify:	
36. Rheumatologic disease[7]	☐Yes ☐No ☐Unknown
37. Immunosuppression	☐Yes ☐No ☐Unknown
38. HIV[8]	☐Yes ☐No ☐Unknown
If yes, on antiretroviral therapy?	☐Yes ☐No ☐Unknown
39. CD4 cell count	☐ <200 cells/µL ☐ 200-499 cells/µL ☐ ≥500 cells/µL ☐ Unknown
40. Other immunosuppression?	☐Yes ☐No ☐Unknown
If yes, specify:	
41. Any other chronic comorbidity	☐Yes ☐No ☐Unknown
If yes, specify:	

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

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

4) OTHER MEDICATIONS USED DURING THIS PREGNANCY

[3] Creatinine >3mg% (265 µmol/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 Hypopituitarism, 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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46. 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 ☐ Rectal ☐ Topical ☐Other:
	☐ Oral ☐ IV ☐ Rectal ☐ Topical ☐Other:
	☐ Oral ☐ IV ☐ Rectal ☐ Topical ☐Other:
	☐ Oral ☐ IV ☐ Rectal ☐ Topical ☐Other:
	☐ Oral ☐ IV ☐ Rectal ☐ Topical ☐Other:
	☐ Oral ☐ IV ☐ Rectal ☐ Topical ☐Other:
	☐ Oral ☐ IV ☐ Rectal ☐ Topical ☐Other:

5) SMOKING, ALCOHOL, DRUGS AND BLOOD TRANSFUSION – RISK FACTORS

47. Smoking during this pregnancy	☐Yes ☐No ☐Unknown	**If yes, specify average per day:** ☐ <10 cigarettes per day ☐ ≥10 cigarettes per day	☐ Other forms of smoking/tobacco Specify:
48. Alcohol consumption during this pregnancy	☐Yes ☐No ☐Unknown	**If yes, specify average alcohol consumption per day** ☐ Less than 1-2 alcoholic drinks[9] per day ☐ 2-5 alcoholic drinks per day ☐ >5 alcoholic drinks per day	**Specify type:**
49. Illicit and recreational drug use during this pregnancy	☐Yes ☐No ☐Unknown	**If yes, specify frequency** ☐ 0-1 occasion per week ☐ 2-5 occasions per week ☐ >5 occasions per week	**Specify all types of drugs used and route of administration:** **Type:** **Route:**
50. Has the patient received a blood transfusion?	☐Yes ☐No ☐Unknown	**Specify/estimate date of last blood transfusion** ☐< 30 days ago ☐>30 days ago	**Reason for transfusion:** _____ _____

Note: If further demographic or epidemiology information is required please use the complementary ZIKV CRF Demographics and Epidemiology

[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	Immunized	Date of last dose (dd/mm/yyyy)
51. Rubella	☐Yes ☐No ☐Unknown	
52. Measles	☐Yes ☐No ☐Unknown	
53. Mumps	☐Yes ☐No ☐Unknown	
54. Acellular pertussis	☐Yes ☐No ☐Unknown	
55. Varicella	☐Yes ☐No ☐Unknown	
56. Tetanus	☐Yes ☐No ☐Unknown	
57. Diphtheria	☐Yes ☐No ☐Unknown	
58. Polio	☐Yes ☐No ☐Unknown	
59. Seasonal influenza	☐Yes ☐No ☐Unknown	
60. Yellow fever	☐Yes ☐No ☐Unknown	
61. Japanese encephalitis	☐Yes ☐No ☐Unknown	
62. Tick-borne encephalitis	☐Yes ☐No ☐Unknown	
63. Dengue virus	☐Yes ☐No ☐Unknown	
64. Hepatitis B	☐Yes ☐No ☐Unknown	
65. Any other vaccinations received during this pregnancy	☐Yes ☐No ☐Unknown If yes, please specify immunization type:	
Any other vaccinations received during this pregnancy	☐Yes ☐No ☐Unknown If yes, please specify immunization type:	

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
66. No confirmed diagnosis	☐ Tick if no diagnosis made		
67. Zika virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
68. Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
69. Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection	__ / __ / ____	

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	☐Probable past infection ☐Negative ☐Not tested ☐Unknown		
70. West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
71. Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
72. Toxoplasmosis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
73. Rubella	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
74. Cytomegalovirus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
75. Herpes Simplex Virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
76. Syphilis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__ / __ / ____	
77. Other (specify):	☐ Confirmed acute infection ☐Probable acute infection		

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	☐Confirmed past infection ☐Probable past infection ☐Negative	__ / __ / ____	
Other (specify):	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	__ / __ / ____	

8) FINAL OUTCOME

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

9) CASE REPORT COMPLETED BY

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