ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS BASELINE AND OUTCOME – (CBO)

Patient'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 sets of Case Report Forms (CRFs) 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 **Child Baseline and Outcome (CBO)** CRF, follow by **Child Acute Symptoms (CAS).** If the patient is admitted to a hospital or has further investigations, complete **Child Hospital Stay (CHS)** and **Child Laboratory Results (CLR)** CRFs. We recommend completing the Neonatal CRF and the Maternal Baseline and Outcome CRF to capture maternal and/or neonatal risk factors. If the patient is admitted to an Intensive Care Unit or Pediatric Intensive Care Unit, complete **Child Intensive Care (CIC)** as well. For follow up visit(s) complete **Child follow up visit(s) (CFU).**

Complete the outcomes sections in the **CBO** CRF 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 patient 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 the patient 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.
- Patient's 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 will be collected using all CRF modules as appropriate.

Sites with very low resources or very high patient numbers may select **Child Baseline and Outcome (CBO)** CRF module only. The decision is up to the site Investigators and may be changed throughout the data collection period. All high quality data are valuable for analysis.

GENERAL GUIDANCE

- The CRFs are designed to collect data obtained through patient examination, for patient or parent/guardian/representative interview and review of hospital notes.
- Patient ID codes should be filled in on all pages of paper CRF forms.
- 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 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

ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS BASELINE AND OUTCOME – (CBO)

Patient's Identification Code : ______________

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.*

CONSENT

Ensure each participant (or their parent or guardian if a child) has given *informed* consent

Date and time of consent (dd/mm/yyyy): __ __ / __ __ / _20_ __ __ Time: __ __: __ __hours
Name and role of the person taking consent : ______________________________________
Signature of person taking consent: ____

1. Geoposition	**Latitude: ____. _______________**	**Longitude: ____. _____________**
2. Name of site/clinic/hospital		
If geoposition not available, state location below		
3. City/town/village:		
4. Country:		
5. Admitted to hospital	☐ Yes ☐ No ☐ Unknown *If yes: (also complete form **CAS**)*	

1) DEMOGRAPHICS

6. Date of Birth [dd/mm/yyyy]	__ / __ / _____
7. Gender	☐ Male ☐ Female
8. Weight	[__|__|__|__] ☐ kg ☐ pounds/ounces **SD***
9. Gestational age at birth	[__|__|__] weeks
10. Birth weight	[__|__|__]kg [__|__|__]pound/ounces
11. Ethnicity (use local classifications)	____

***SD** Plot weight on appropriate growth curve according to national guidelines

MATERNAL DEMOGRAPHICS: please complete Maternal Baseline and Outcome CRF

BIRTH AND NEONATAL DETAILS: please complete Neonatal Baseline and Outcome CRF

2) TRAVEL HISTORY (any city, town, village or region visited in the last 4 weeks. Include maternal travel in case child < 2 weeks of age)

12. Any history of travel (local/national/international) ☐ **Yes** ☐ **No**	**Approximate first and last date** [dd/mm/yyyy]	**Total number of days**	**Includes overnight stay**
13. Main home address: ___________________	__/__/____ to __/__/____		☐ Yes ☐ No
14. *If yes:* Other places visited:	__/__/____ to __/__/____		☐ Yes ☐ No

ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS BASELINE AND OUTCOME – (CBO)

Patient's Identification Code : _______________

	__/__/____ to __/__/____		☐ Yes ☐ No
	__/__/____ to __/__/____		☐ Yes ☐ No
	__/__/____ to __/__/____		☐ Yes ☐ No
	__/__/____ to __/__/____		☐ Yes ☐ No

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

3) CHRONIC COMORBIDITIES/PAST MEDICAL HISTORY

15. Chronic cardiovascular disease[1]	☐Yes ☐No ☐Unknown
16. Chronic pulmonary disease[2]	☐Yes ☐No ☐Unknown
17. Blood disorders	☐Yes ☐No ☐Unknown
If yes, please specify:	
18. Chronic renal/kidney disease[3]	☐Yes ☐No ☐Unknown
19. Gastro-intestinal and/or liver disease[4]	☐Yes ☐No ☐Unknown
20. Chronic neurological disease[5]	☐Yes ☐No ☐Unknown
If yes, please specify:	
21. Paralysis	☐Yes ☐No ☐Unknown
If yes, please specify body parts affected:	
22. Metabolic diseases	☐Yes ☐No ☐Unknown
If yes, please specify:	
23. Endocrine disease	☐Yes ☐No ☐Unknown
If yes, please specify:	☐Yes ☐No ☐Unknown
24. Rheumatological and/or auto-immune disease[6]	☐Yes ☐No ☐Unknown
If yes, please specify:	
25. HIV[7]	☐Yes ☐No ☐Unknown
If yes, on antiretroviral therapy?	☐Yes ☐No ☐Unknown
26. CD4 cell count	☐ <200 cells/µL ☐200-499 cells/µL ☐ ≥500 cells/µL ☐Unknown
27. Other immunosuppression?	☐Yes ☐No ☐Unknown
If yes, please specify:	
28. Any other chronic comorbidity (please specify):	☐Yes ☐No ☐Unknown

---

[1] Includes cerebrovascular disease (stroke), hypertension (Systolic > p 99), rheumatic heart disease, congenital heart disease and heart failure, cardiac arrhythmias.

[2] Chronic lung diseases that cause limitations in lung airflow (such as congenital lung abnormalities, broncho-pulmonary dysplasia, allergic rhinitis/sinusitis, recurrent or chronic airway infections or multiple induced or viral induced wheeze ("asthma"). http://www.who.int/respiratory/asthma/en/ and http://www.who.int/respiratory/other/en/

[3] Reno-genito-urinary tract malformations, renal insufficiency including dialysis, transplantation, recurrent urinary tract infections or pyelonephritis

4 Includes (congenital) liver disorders or cirrhosis, hepatitis, (congenital) gastro-intestinal disease. Cirrhosis with PHT +/- variceal bleeding

5 Disorders of the nervous system e.g. epilepsy, congenital cerebral malformations, peri-natal asphyxia, cerebral palsy.

7 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.

ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS BASELINE AND OUTCOME – (CBO)

Patient's Identification Code : _______________

4) MEDICATION HISTORY

29. Medication history Please list **all** other medications taken by the patient in the 4 weeks before this illness including non-prescription, herbal non-licensed remedies, or vitamins. Please list generic names if possible.

Type of medication	**Name of medication** (generic name)	**Dose** (fluids indicate volume)	**Frequency** (per day)	**Start date** (dd/mm/ yyyy)	**Number of days**	**Route of administration**
						☐IV ☐Oral ☐Rectal ☐Other:
						☐IV ☐Oral ☐Rectal ☐Other:
						☐IV ☐Oral ☐Rectal ☐Other:
						☐IV ☐Oral ☐Rectal ☐Other:
						☐IV ☐Oral ☐Rectal ☐Other:

5) OTHER RISK FACTORS

30. Parental tobacco use?	☐Yes ☐No ☐Unknown	**If yes, specify average per day:** ☐ <10 cigarettes per day ☐ ≥10 cigarettes per day	☐ Other forms of smoking/tobacco Specify:
31. Blood transfusion?	☐Yes ☐No ☐Unknown	**Specify/estimate date of last blood transfusion** ☐< 30 days ago ☐>30 days ago	**Reason for transfusion:** ____________________________ ____________________________
32. Socio-economic status of parents (according to national guidelines)	☐Low ☐Low Middle ☐Middle ☐Upper Middle ☐High		
33. Feeding	☐Breast fed ☐Formula fed ☐ Both		

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

6) IMMUNIZATION HISTORY

Vaccine	**Immunized**	**Date of last dose** (dd/mm/yyyy)
34. Rubella	☐Yes ☐No ☐Unknown	
35. Measles	☐Yes ☐No ☐Unknown	

Patient's Identification Code : _______________

36. Mumps	☐Yes ☐No ☐Unknown	
37. Acellular pertussis	☐Yes ☐No ☐Unknown	
38. Varicella	☐Yes ☐No ☐Unknown	
39. Tetanus	☐Yes ☐No ☐Unknown	
40. Diphtheria	☐Yes ☐No ☐Unknown	
41. Polio	☐Yes ☐No ☐Unknown	
42. Seasonal influenza	☐Yes ☐No ☐Unknown	
43. Yellow fever	☐Yes ☐No ☐Unknown	
44. Japanese encephalitis	☐Yes ☐No ☐Unknown	
45. Tick-borne encephalitis	☐Yes ☐No ☐Unknown	
46. Dengue virus	☐Yes ☐No ☐Unknown	
47. Hepatitis B	☐Yes ☐No ☐Unknown	
48. Haemophilus influenza type B	☐Yes ☐No ☐Unknown	
49. Meningococcus C	☐Yes ☐No ☐Unknown	
50. Any other vaccinations received	☐Yes ☐No ☐Unknown (if yes, specify immunization type):	
Any other vaccinations received	☐Yes ☐No ☐Unknown (if yes, specify immunization type):	

7) IMAGING (if available)

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

Imaging	**Results**	**If abnormal, please summarize key results:**	**Images attached**	**Report attached**
51. Cranial ultrasound scan	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
52. MRI brain (record only if done as part of routine care)	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
53. CT brain (record only if part of routine care)	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
54. Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No

ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS BASELINE AND OUTCOME – (CBO)

Patient's Identification Code : ______________

8) FINAL DIAGNOSIS

Pathogen	Diagnosis	Date of onset (dd/mm/yyyy)	Comment
55. No confirmed diagnosis	☐ Tick if no diagnosis made		
56. Zika virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/ ____/ _____	
57. Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/ ____/ _____	
58. Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/ ____/ _____	
59. West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/ ____/ _____	
60. Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/ ____/ _____	
61. Other (specify): ___________________	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	__/ __/ ____	

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

9) FINAL OUTCOME

Outcome	**Details**
63. Date of discharge/going home [dd/mm/yyyy]	__ / __ / ______
64. Outcome at discharge/going home	☐Discharged/sent home without sequelae ☐Discharged/ sent home with sequelae ☐Deceased ☐Unknown
65. If discharged/ sent home with sequelae, describe:	
66. If deceased, specify date of death [dd/mm/yyyy]	__ / ___ / ________
67. Zika virus infection	☐Positive ☐Probable ☐Negative ☐Unknown ☐Not tested
68. Diagnosis confirmed by	☐Lab. confirmed local hospital laboratory ☐Lab. confirmed by national reference laboratory ☐Lab. confirmed by international reference laboratory ☐Other, please detail: ______________________________

69. Other outcomes, specify all:

Infant abnormality			
Microcephaly	☐Present	☐Absent	
Facial disproportion	☐Present	☐Absent	
Hearing impairments	☐Present	☐Absent	
Visual impairments	☐Present	☐Absent	
Dysphagia	☐Present	☐Absent	
Calcifications - CNS imaging	☐Present	☐Absent	
Epilepsy and seizures	☐Present	☐Absent	
Spasticity/contractures	☐Present	☐Absent	
Neurological reflexes	☐Present	☐Absent	
Cerebral palsy	☐Present	☐Absent	
Other, specify:			

Patient's Identification Code : ______________

10) CASE REPORT FORM COMPLETED BY

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