ZIKA VIRUS CASE REPORT FORMS – CHILD 0-5 YEARS FOLLOW UP VISIT(S) – (CFU)

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

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

1) CHILD DEMOGRAPHICS

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

NEONATE MEASURMENTS AT BIRTH: please complete Neonatal Baseline and Outcome CRF if this has not been done yet.

MATERNAL DEMOGRAPHICS: please complete Maternal Baseline and Outcome CRF if this has not been done yet.

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

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2) CHILD MEASUREMENTS AT FOLLOW-UP VISIT

12. Current weight	____	grams	____	pounds	____	ounces
13. Current length (crown to heel)	____	cm	____	inches	☐ unknown	
14. Current Head circumference (occipito-frontal)	____	cm	____	inches	☐ unknown	

Plot metrics in growth curve as per your national guidelines and record the standard deviations above (indicated with "+") or below (indicated with "-") the mean for age and sex	**15. Current weight** _____ SD	**16. Current length** _____ SD	**17. Current head circumference** _____ SD

3) (BIRTH) ABNORMALITIES

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

18. Fontanelle present	**Anterior:** ☐Yes ☐No ☐Unknown	**Posterior:** ☐Yes ☐No ☐Unknown	**Bulging:** ☐Yes ☐No ☐Unknown
19. Abnormal skull shape	☐Yes ☐No ☐Unknown	☐ Oxicefalia ☐ Plagiocefalia ☐ Trigocefalia ☐ Escafocefalia ☐ Acrocefalia	

If yes, circle most appropriate depiction[1]:

Oxicefalia

Plagiocefalia

Trigocefalia

Escafocefalia

Acrocefalia

[1]http://www.himfg.edu.mx/descargas/documentos/EDI/ManualdeExploracionNeurologicaparaNinosMenoresde5enelPrimerySegundoNiveldeAtencion.pdf

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20. Sloping forehead	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
21. Craniosynostosis	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
22. Redundant skin on skull at birth	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
23. Facial disproportion	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
24. Nasal abnormalities **25. Flat nasal bridge** **26. Anteverted nares** **27. Other nasal abnormalities**	☐Yes ☐No ☐Unknown ☐Yes ☐No ☐Unknown ☐Yes ☐No ☐Unknown ☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
28. Orofacial clefts	☐Yes ☐No ☐Unknown ☐ Cleft lip ☐ Cleft palate ☐ Both ☐ No	☐left ☐right ☐middle ☐bilateral
29. Eye abnormalities	☐Yes ☐No ☐Unknown ☐Anophthalmia ☐Microphthalmia	☐ **Other (describe):**
30. Ear abnormalities	☐Yes ☐No ☐Unknown ☐ Anotia (absent ear/s) ☐ Microtia (small ear/s)	☐ **Other (describe):**
31. Hemangiomas	☐ Present ☐ Absent	○ Facial ○ Rest of body Number of them:_____
32. Neural tube defects	☐Yes ☐No ☐Unknown ☐ Spina bifida ☐ Meningocele ☐ Anencephaly	☐ **Other (describe):**
33. Scoliosis **34. Barrel-like chest**	☐Yes ☐No ☐Unknown ☐Yes ☐No ☐Unknown	
35. Upper Limb abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown Arthrogryposis ☐Yes ☐No Amyoplasia ☐Yes ☐No If yes: ☐Distal ☐Syndromic Hyperextension ☐Yes ☐No If yes, indicate joints: _____ _____ Contractures ☐Yes ☐No If yes, indicate joints: _____ _____	☐**Other (describe):**

Patient's Identification Code : _____

36. Hand abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown o Clinodactyly ☐ Unilateral ☐ Bilateral o Missing digits ☐ Unilateral ☐ Bilateral o Extra digits ☐ Unilateral ☐ Bilateral o Camptodactyly ☐ Unilateral ☐ Bilateral o Nail hypoplasia/aplasia o Adducted thumb o Bilateral simian crease	☐**Other (describe):**
37. Lower Limb abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown Arthrogryposis ☐Yes ☐No Amyoplasia ☐Yes ☐No If yes: ☐Distal ☐Syndromic Hyperextension ☐Yes ☐No If yes, indicate joints): _____ _____ Joint dislocation/subluxation ☐Yes ☐No If yes, indicate joints): _____ _____ Contractures ☐Yes ☐No If yes, indicate joints): _____ _____	☐**Other (describe):**
38. Feet abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown o Widely spaced toes ☐ Unilateral ☐Bilateral o Missing toes ☐ Unilateral ☐Bilateral o Extra toes ☐ Unilateral ☐Bilateral o Clubfoot ☐ Unilateral ☐Bilateral o Nail ☐ Unilateral ☐Bilateral	☐**Other (describe):**
39. Umbilical hernia	☐ Present ☐ Absent	
40. Gastroschisis	☐Yes ☐No ☐Unknown	
41. Omphalocele	☐Yes ☐No ☐Unknown	
42. Any other significant abnormalities present **If yes, specify/describe:**	☐Yes ☐No ☐Unknown **Cardiac:** ☐Yes ☐No ☐Unknown **Renal:** ☐Yes ☐No ☐Unknown	☐**Other (describe):**

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	Organomegaly (enlarged liver/spleen) ☐Yes ☐No ☐Unknown	
43. Known familial genetic disorders	☐Yes ☐No ☐Unknown	**If yes, please specify:**
44. Other Syndromic abnormalities identified by Physician	☐Yes ☐No ☐Unknown	**If yes, please specify:**

4) OTHER TEST AND/OR EXAMINATION

Test	**Result**	**If abnormal, please describe abnormality:**
45. Fundoscopy	☐Normal ☐Abnormal ☐Not Done	
46. Red reflex	☐Present ☐Absent ☐Not Done	
47. Cataract	☐Normal ☐Abnormal ☐Not Done	
48. Chorioretinitis	☐ Absent ☐ Present ☐ Examination Not Done	
49. Hearing test	☐Normal ☐Abnormal ☐Not Done	**please specify test used:**
50. Congenital heart defects	☐Yes ☐No ☐Unknown	**If yes, specify:**
51. Any other significant findings	☐Yes ☐No	**If yes, please specify:**

5) GENERAL

52. Feeding (please tick all appropriate)	o breast fed o formula fed o both o assisted (e.g. naso-gastric tube)	**Please specify how many months of breastfeeding to date:**
53. Does the child struggle to drink the required amount for his/her age?	☐Yes ☐No ☐Unknown	**If yes, please specify:**

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54. Difficulty swallowing (dysphagia)?	☐Yes ☐No ☐Unknown	
55. Does the child drink more than the required amount for his/her age?	☐Yes ☐No ☐Unknown	**If yes, please specify:**
56. Type of cry	☐Strong normal cry ☐Weak, high-pitched or continuous cry ☐Not crying ☐Other:	

6) BASELINE OBSERVATIONS during follow-up visit

**If a neuromuscular and/or neurodevelopmental assessment is required, please complete an additional examination using the Neurodevelopmental/neuromuscular assessment tool indicated as per your hospital guidelines and protocol.*

57. Date (dd/mm/yyyy)		**__ __ / __ __ / 20 __ __**	
General physical examination			
58. Maximum Temperature		____.__°C or _____ Fahrenheit ☐Oral ☐Tympanic ☐Axillary ☐Anal ☐Skin ☐Other (specify):	
59. Respiratory rate			breaths/minute ☐ not done
60. Heart rate			beats/minute ☐ not done
61. Capillary refill time (central)			Seconds ☐ not done
62. Peripheral O_2 saturation (SpO_2)			% ☐ not done
63. Cardiovascular system	☐Normal ☐Abnormal ☐Unknown	☐Murmur ☐Other (specify) :	
64. Respiratory system	☐Normal ☐Abnormal ☐Unknown	If abnormal, describe:	
65. Gastrointestinal system	☐Normal ☐Abnormal ☐Unknown	☐Jaundice ☐Abdominal tenderness ☐Hepatomegaly ☐Splenomegaly ☐Other (specify):	
66. Edema	☐Yes ☐No ☐Unknown	**If yes, describe:**	
67. Cryptorchidism	☐Yes ☐No ☐Unknown ☐Not applicable		
68. Type of cry (if child < 3 months of age)	☐Strong normal cry ☐Weak, high-pitched or continuous cry ☐Not crying ☐Other:		

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Neurological examination *			
69. Tonic neck reflex (if child < 3 months of age)	☐ Asymmetrical ☐ Symmetrical ☐Left ☐Right ☐Absent ☐Not Done		
70. Sucking reflex (present if child < 6 months)	☐ Present ☐ Absent		
71. Grasp reflex (present in children < 6 months)	**Left foot** ☐ Present ☐ Absent	**Right foot** ☐ **Present** ☐ Absent	
	Left hand ☐ Present ☐ Absent	**Right hand** ☐ **Present** ☐ Absent	
72. Moro reflex (if child < 5 months)	☐Present ☐Absent ☐Not Done	☐Symmetrical ☐Asymmetrical	
73. Rooting reflex (if child < 4 months)	☐Present ☐Absent ☐Not Done		
74. Deep tendon reflexes		**Left**	**Right**
	Biceps	☐Present ☐Absent ☐Not Done	☐Present ☐Absent ☐Not Done
	Brachioradialis	☐Present ☐Absent ☐Not Done	☐Present ☐Absent ☐Not Done
	Triceps	☐Present ☐Absent ☐Not Done	☐Present ☐Absent ☐Not Done
	Patellar	☐Present ☐Absent ☐Not Done	☐Present ☐Absent ☐Not Done
	Achilles tendon	☐Present ☐Absent ☐Not Done	☐Present ☐Absent ☐Not Done
75. Muscle tone	☐Normal ☐Hypertonic ☐Hypotonic	If hypertonic, specify which limbs involved:	
76. Extremity movements	☐Symmetrical ☐Asymmetrical ☐Unknown		
77. Seizure(s)	☐ General ☐ Focal ☐No ☐Unknown	Fever-associated: ☐Yes ☐No ☐Unknown	
	If seizures are present, describe: Frequency: _ _ times per hour ☐ day ☐ week ☐ month Average length: _ _ seconds ☐ minutes ☐ hours ☐ continuous Are seizures still ongoing at time of follow-up? ☐Yes ☐No ☐Unknown		

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	☐Other (specify):	
78. Paralysis	☐ General ☐ Ascending ☐ No ☐ Unknown	**If yes, describe:**
79. Contractures	☐Yes ☐No ☐Unknown	**If yes, describe:**

80. Babinski reflex (plantar reflex)	**Right foot** ☐Upgoing ☐Downgoing ☐Equivocal ☐Not Done	**Left foot** ☐Upgoing ☐Downgoing ☐Equivocal ☐Not Done
81. Other abnormal movements* e.g. writhing movements	☐Yes ☐No ☐Unknown	**If yes, describe:**

7) IMAGING (if available)

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

Imaging	**Results**	**If abnormal, please summarize key results from report:**	**Images attached**	**Report attached**
82. Cranial ultrasound scan	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
83. MRI brain (record only if part of routine care)	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
84. CT brain (record only if part of routine care)	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
85. Other (specify type of test and part of body):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
Other (specify type of test and part of body):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No

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8) MEDICATIONS

86. List medications administered regularly as prescribed by treating physician. Include antibiotics, antivirals, corticosteroids, immunoglobulin, anticonvulsants, diuretics or others.

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:

9) CHILD HOSPITAL ADMISSION

Fill out separately for each relevant hospital admission

87. Recent hospital admissions?	☐Yes ☐No ☐Unknown		
88. If yes, state the name of the hospital(s)			
89. City			
90. Reason of admission			
91. Date of admission (dd/mm/yyyy)	**____ / ____ / 20 ____**	**92. Length of stay** (days)	_____ days ☐Unknown
93. Diagnosis at discharge			

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94. How many times was the child admitted for this reason?	
95. Was the child admitted to intensive care? (ITU/PICU/NICU/PHDU)	☐Yes ☐No ☐Unknown
If yes, please also complete the Zika virus Case Report Form (CRF) – Child 0-5 Intensive Care module	

10) DIAGNOSTIC OUTCOMES CHILD

Have any of the following diagnoses been made? 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	Comment
96. No confirmed diagnosis	☐ Tick if no diagnosis made	
97. Zika virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
98. Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
99. Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
100. West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
101. Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	

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102. Toxoplasmosis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
103. Rubella	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
104. Cytomegalovirus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
105. Herpes Simplex virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
106. Other (specify):	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	
Other (specify):	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	

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14) OUTCOME AT FOLLOW-UP VISIT

107. Date of last contact (dd/mm/yyyy) : _ _/_ _/_ _ _ _

108. Date last seen alive (dd/mm/yyyy): _ _/_ _/_ _ _ _

☐Alive
☐Dead Date of death (dd/mm/yyyy): _____

109. Describe/ specified the evolution of the observations in section 8:
_____
_____
_____
_____

110. Score Neurological Examination at follow-up visit: _____ Specify:_____
Test:_____

Other neurodevelopmental test score at this follow-up visit: _____

111. Presence / absence of specific features at this follow-up visit:

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:			

15) CASE REPORT FORM COMPLETED BY

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