



# ZIKA VIRUS CASE REPORT FORMS – ADULT AND CHILD >5YEARS LABORATORY RESULTS – (ACLR)



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 **Adult/Child Baseline and Outcome (ACBO)** CRF, followed by **Adult/Child Laboratory Results (ACLR)** CRFs. If the patient is admitted to an Intensive Care Unit or Pediatric Intensive Care Unit, complete **Adult/Child Intensive Care (ACIC)** as well. If the patient is admitted to a hospital or has further investigations, complete **Adult/Child Acute Symptoms (ACAS)**, **Adult/Child Hospital Stay (ACHS)** and **Adult/Child Laboratory Results (ACLR)** for every day of admission.

Complete the outcomes sections in the **ACBO** 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 have been 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 the Adult/Child Baseline and Outcome (ACBO) 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 (o) 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](mailto:gail.carson@ndm.ox.ac.uk)



# ZIKA VIRUS CASE REPORT FORMS – ADULT AND CHILD >5YEARS LABORATORY RESULTS – (ACLR)



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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.*

## 1) LABORATORY RESULTS

Record all values available ≤24 hours of presentation/admission. Use the most abnormal value per day. If not available, enter ND=not done, or UK=Unknown under value. For repeat testing, copy this page and ensure date of testing and patient IDs are indicated on each page.

<b>1. Date of sampling</b> (dd/mm/yyyy)	__ / __ / 20 __		
<b>Test</b>		<b>Value</b>	<b>Specify unit, if other specify unit used.</b>
<b>Inflammatory markers</b>			
<b>2. C-reactive protein</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> mg/L <input type="checkbox"/> other:_____
<b>3. Erythrocyte sedimentation rate</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> mm/hr <input type="checkbox"/> other:_____
<b>4. Procalcitonin</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> ng/mL <input type="checkbox"/> other:_____
<b>Hematology</b>			
<b>5. Hemoglobin</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> g/L <input type="checkbox"/> g/dL <input type="checkbox"/> other:_____
<b>6. Hematocrit</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> % <input type="checkbox"/> other:_____
<b>7. RBC count</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> x10 <sup>9</sup> /L <input type="checkbox"/> x10 <sup>3</sup> /μL <input type="checkbox"/> other:_____
<b>8. MCV</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> μm <sup>3</sup> <input type="checkbox"/> other:_____
<b>9. White blood cell count</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> x10 <sup>9</sup> /L <input type="checkbox"/> x10 <sup>3</sup> /μL <input type="checkbox"/> other:_____
<b>10. Neutrophils</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> 10 <sup>3</sup> /mm <sup>3</sup> <input type="checkbox"/> % <input type="checkbox"/> other:_____
<b>11. Lymphocytes</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> 10 <sup>3</sup> /mm <sup>3</sup> <input type="checkbox"/> % <input type="checkbox"/> other:_____
<b>12. Monocytes</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> 10 <sup>3</sup> /mm <sup>3</sup> <input type="checkbox"/> % <input type="checkbox"/> other:_____
<b>13. Eosinophils</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> 10 <sup>3</sup> /mm <sup>3</sup> <input type="checkbox"/> % <input type="checkbox"/> other:_____
<b>14. Basophils</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> 10 <sup>3</sup> /mm <sup>3</sup> <input type="checkbox"/> % <input type="checkbox"/> other:_____
<b>15. Platelets</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> x10 <sup>9</sup> /L <input type="checkbox"/> x10 <sup>3</sup> /μL <input type="checkbox"/> other:_____
<b>16. APTT</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> seconds
<b>17. PT (seconds)</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> seconds
<b>18. Blood film</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		Describe results: _____
<b>Biochemistry</b>			
<b>19. Urea nitrogen</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL <input type="checkbox"/> other:_____
<b>20. Creatinine</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> μmol/L <input type="checkbox"/> mg/dL <input type="checkbox"/> other:_____
<b>21. Sodium</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> mmol/L <input type="checkbox"/> other:_____
<b>22. Potassium</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> mmol/L <input type="checkbox"/> other:_____
<b>23. Total protein</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> g/dL <input type="checkbox"/> other:_____
<b>24. Albumin</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> g/L <input type="checkbox"/> other:_____
<b>25. Bilirubin</b>	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown		<input type="checkbox"/> μmol/L <input type="checkbox"/> mg/dL <input type="checkbox"/> other:_____



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26. AST/SGOT	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> U/L	<input type="checkbox"/> other: _____
27. ALT/SGPT	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> U/L	<input type="checkbox"/> other: _____
28. GGT	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> U/L	<input type="checkbox"/> other: _____
29. ALP	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> U/L	<input type="checkbox"/> other: _____
30. Calcium	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> mmol/L	<input type="checkbox"/> other: _____
31. Phosphate	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> mg/dL	<input type="checkbox"/> other: _____
32. Magnesium	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> mmol/L	<input type="checkbox"/> other: _____
33. Amylase	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> U/L	<input type="checkbox"/> other: _____
34. Glucose	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL	<input type="checkbox"/> other: _____
35. Creatine kinase	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> U/L	<input type="checkbox"/> other: _____
36. Other biochemistry result (specify):	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> Unit: _____	
Other biochemistry result (specify):	<input type="checkbox"/> Yes <input type="checkbox"/> Not done <input type="checkbox"/> Unknown	<input type="checkbox"/> Unit: _____	
If yes , describe results:			

## 2) CSF SAMPLE (if available as part of routine care)

37. Lumbar puncture performed? Yes No Unknown

If yes, complete tables below. If no, CSF sample skip to section 3.

38. Date of lumbar puncture (dd/mm/yyyy): \_\_\_ / \_\_\_ / 20\_\_

39. CSF appearance	<input type="checkbox"/> Clear and colorless <input type="checkbox"/> Cloudy <input type="checkbox"/> Blood stained <input type="checkbox"/> Frank blood/traumatic tap (only for pediatrics) <input type="checkbox"/> Unknown
40. Gram stain	<input type="checkbox"/> No organisms seen <input type="checkbox"/> Organisms seen <input type="checkbox"/> Not done If organism seen, describe the gram morphology:

\*Must be taken within 4 hours of the lumbar puncture, record capillary blood glucose if laboratory glucose not done

Test	Value	Specify unit
41. Opening pressure		mmH2O
42. CSF protein		<input type="checkbox"/> mg/dl <input type="checkbox"/> other: _____
43. CSF glucose		<input type="checkbox"/> mmol/l <input type="checkbox"/> other: _____
44. Plasma glucose at time of LP*		<input type="checkbox"/> mmol/l <input type="checkbox"/> other: _____
45. CSF RBC count		<input type="checkbox"/> per mm <sup>3</sup> <input type="checkbox"/> other: _____
46. CSF WBC count		<input type="checkbox"/> per mm <sup>3</sup> <input type="checkbox"/> other: _____
47. Lymphocytes		<input type="checkbox"/> % <input type="checkbox"/> other: _____
48. Neutrophils		<input type="checkbox"/> % <input type="checkbox"/> other: _____



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<b>49. Other (specify):</b>		<input type="checkbox"/> unit: ____
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### 3) PATHOGEN TESTING

Record all pathogen testing carried out for differential diagnosis. Record all results available from local, regional or other laboratories. For additional sample type, add to other, or copy in additional rows as needed. For additional follow up sampling, copy table.

Sample type	Pathogen	Date of sampling (dd/mm/yyyy)	Method	Results	Methods/Assays used	Comments
<b>50. Blood</b>		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
<b>Blood</b>		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
<b>51. Urine</b>		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
<b>Urine</b>		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
<b>52. <input type="checkbox"/>Saliva swab</b> <b>53. <input type="checkbox"/>Throat swab</b> <b>54. <input type="checkbox"/>Nasal swab</b>		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Other: _____			
<b>55. CSF</b>		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			



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CSF		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
56. Stool / Feces		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
Stool / Feces		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
57. Other (specify):		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
Other (specify):		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			
Other (specify):		__/__/20__	<input type="checkbox"/> PCR <input type="checkbox"/> Culture <input type="checkbox"/> Serology <input type="checkbox"/> Microscopy <input type="checkbox"/> Other: _____			

## 4) CASE REPORT FORM COMPLETED BY

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