ZIKA VIRUS CASE REPORT FORMS – RETURNING TRAVELLER LABORATORY RESULTS – (TLR)

Patient's Identification Code : _____

Introduction

This standardized Case Report Form (CRF) is part of a suite of data collection tools for ZIKV infection that has been created by ISARIC.

DESIGN OF THIS CASE REPORT FORM (CRF)

For returning travellers there are FOUR sets of Case Report Forms (CRFs) that may be used in combination – "Returning Traveller Baseline and Outcome" (TBO), "Returning Traveller Acute Symptoms" (TAS), "Returning Traveller Laboratory Results" (TLR) and "Returning Traveller Intensive Care" (TIC).

These CRFs are to be used at enrolment, for the non-pregnant returning traveller (adult or child) who has visited a country affected by the current Zika virus (ZIKV) outbreak within 15 days of onset of symptoms.
If the patient is pregnant or a neonate complete the ZIKV Maternal and Neonate Case Report Forms respectively.
If the patient has acquired ZIKV due to sexual contact with a traveller, please refer to the Adult and Child collection of CRFs.
For additional Demographic and Epidemiological data fields, please refer to the ZIKV Epidemiology and Demographics CRF.
For all studies, we recommend completing a minimum of the **Returning Traveller Baseline and Outcome (TBO)** CRF, followed by **Returning Traveller Laboratory Results (TLR)** CRF. If the patient is admitted to an Intensive Care Unit or High Dependency Care Unit, complete **Returning Traveller Intensive Care (TIC)** CRF.

For travellers presenting with acute symptoms, complete **Returning Traveller Acute Symptoms (TAS).**

HOW TO USE THIS CRF

When completing the CRF modules, please note 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 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 identifiable information should not be recorded on the CRFs.
- Patients' hospital ID and contact details are recorded on a separate contact list to allow later follow up. This information 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. The decision is up to the site Investigators and may be changed throughout the data collection period.

GENERAL GUIDANCE

- We recommend writing clearly in black or blue ink, using BLOCK-CAPITAL LETTERS.
- Do NOT leave sections blank, except for where the instructions say to skip a section based on certain responses.
- The CRF is designed to collect data obtained through patient examination and chart review.
- Patient ID codes should be filled in on all pages of paper CRF forms.
- 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).
- IMPORTANT: Please mark the 'Unknown' box if the answer to a particular question is not known. **Do not leave these sections blank.**
- Some sections have blank areas where you can write additional information. To permit standardized data entry, please avoid writing additional information outside of these areas.
- 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 a single patient 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, or 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 ZIKV. 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 operating 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.

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

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24. Albumin	☐Yes ☐Not done ☐Unknown		☐g/L ☐other:_____
25. Bilirubin	☐Yes ☐Not done ☐Unknown		☐µmol/L ☐mg/dL ☐other:_____
26. AST/SGOT	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
27. ALT/SGPT	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
28. GGT	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
29. ALP	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
30. Calcium	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐other:_____
31. Phosphate	☐Yes ☐Not done ☐Unknown		☐mg/dL ☐other:_____
32. Magnesium	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐other:_____
33. Amylase	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
34. Glucose	☐Yes ☐Not done ☐Unknown		☐mmol/L ☐mg/dL ☐other:_____
35. Creatine kinase	☐Yes ☐Not done ☐Unknown		☐U/L ☐other:_____
36. Other biochemistry result (specify):	☐Yes ☐Not done ☐Unknown		☐Unit:_____
Other biochemistry result (specify):	☐Yes ☐Not done ☐Unknown		☐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 next section

38. Date [dd/mm/yyyy]: ___ / ____ / _____

39. CSF appearance	☐Clear and colorless ☐Cloudy ☐Blood stained ☐Frank blood/traumatic tap(only for pediatrics) ☐Unknown
40. Gram stain	☐no organism seen ☐Organism seen ☐Not done If organism seen, describe the gram morphology:

Test	Value	Specify unit	
41. Opening Pressure		☐mmH2O	
42. CSF protein		☐mg/dl	☐other: ___
43. CSF glucose		☐mmol/l	☐other: ___

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44. Plasma glucose at time of LP*		☐mmol/l	☐other: ___
45. CSF RBC count		☐per mm^3	☐other: ___
46. CSF WBC count		☐per mm^3	☐other: ___
47. Lymphocytes		☐%	☐other: ___
48. Neutrophils		☐%	☐other: ___
49. Other (specify):		☐unit: ___	

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

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
50. Guthrie test (Dried blood spot) Only for under 1 year old		__/__/____	☐PCR ☐Serology ☐Other: _____			
Guthrie test (Dried blood spot) Only for under 1 year old		__/__/____	☐PCR ☐Serology ☐Other: _____			
51. Blood		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Blood		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other:			

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			_____			
52. Urine		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Urine		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
53. ☐Saliva swab **54. ☐Throat swab** **55. ☐Nasal swab**		__/__/____	☐PCR ☐Culture ☐Other: _____			
56. CSF		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
CSF		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
57. Stool / Feces		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Stool/Feces		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy			

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			☐Other: _____			
58. Other (specify):		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Other (specify):		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Other (specify):		__/__/____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			
Other (specify):		__/__/_____	☐PCR ☐Culture ☐Serology ☐Microscopy ☐Other: _____			

4) REGIONAL REFERENCE LABORATORY RESULTS

Please record details of any samples analyzed in the regional reference laboratory.

59. Name of regional reference lab:_____

60. City/town:_____

61. Sampling date (dd/mm/yyyy**): __ / __ / 20 __**

Sample type	Method	Pathogen tested for	Results	Comments, methods/assays used
	☐PCR ☐Culture ☐Serology ☐Other: _____			
	☐PCR ☐Culture ☐Serology			

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	☐Other: _____			
	☐PCR ☐Culture ☐Serology ☐Other: _____			

5) CASE REPORT FORM COMPLETED BY

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