ZIKA VIRUS CASE REPORT FORMS – RETURNING TRAVELLER ACUTE SYMPTOMS – (TAS)

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. Geoposition	**Latitude:** ___ _ . _____	**Longitude:** ___ _ . _____	
2. Name of site/clinic/hospital			
If geoposition not available:			
3. City/town/village:			
4. Country:			
5. Admitted to hospital	☐ Yes ☐ No ☐ Unknown		
6. If yes, date of admission (dd/mm/yyyy)	__ / __ / 20 __	**7. Date of discharge**	__ / __ / 20 __ ☐Unknown
8. Name of hospital admitted to and town/city:			
9. Date of onset of first symptoms (dd/mm/yyyy)	__ / __ / 20 __		

1) BASELINE MEASUREMENTS

10. Weight	_____ ☐kg ☐pounds/ounces
11. Height	_____ ☐cm ☐feet/inches
12. Weight loss	☐Yes ☐No ☐Unknown
If yes, specify lost during this current episode of illness	_____ ☐kg ☐pounds/ounces

2) DAILY OBSERVATIONS DURING ADMISSION EPISODE

During hospital admission, **complete with the (most abnormal) value within the previous 24 hours.** This form can be copied and completed as many days as required.

13. DATE: dd/mm/yyyy						
14. Type of ward e.g. Infectious Diseases (ID); Intensive Care (ICU); Other (includes general ward)	☐ID ☐General ward ☐ICU ☐Other: _____	☐ID ☐General ward ☐ICU ☐Other: _____	☐ID ☐General ward ☐ICU ☐Other: _____	☐ID ☐General ward ☐ICU ☐Other: _____	☐ID ☐General ward ☐ICU ☐Other: _____	☐ID ☐General ward ☐ICU ☐Other: _____
15. Maximum Temperature ☐°C *or* ☐°F						
16. Respiratory Rate breaths/minute						

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17. Heart Rate beats/minute						
18. Systolic BP mmHg						
19. Diastolic BP mmHg						
20. Peripheral O_2 Saturation (SpO_2) %						
21. Glasgow Coma Score (out of 15) **OR**						
22. AVPI: (LOWEST Consciousness) **A**lert, **V**erbal stimuli, **P**ainful stimuli, **U**nresponsive	☐*A* ☐ *V* ☐*P* ☐*U*	☐*A* ☐ *V* ☐*P* ☐*U*	☐*A* ☐ *V* ☐*P* ☐*U*	☐*A* ☐ *V* ☐*P* ☐*U*	☐*A* ☐ *V* ☐*P* ☐*U*	☐*A* ☐ *V* ☐*P* ☐*U*
23. Lymphadenopathy	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
If yes, specify : C= **C**ervical **O=Occipital, R=Retro-auricular, G=General**						
24. Enlarged Liver	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
25. Enlarged Spleen	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
26. Amnesia	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
27. Confusion/ disorientation	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
28. Altered behavior or personality	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
29. Headache	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
30. Photophobia	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
31. Neck stiffness	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
32. Seizures	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK

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If yes, specify G=generalized, F=focal, UK=Unknown						
33. Paralysis	☐General ☐Ascending ☐No ☐UK	☐General ☐Ascending ☐No ☐UK	☐General ☐Ascending ☐No ☐UK	☐General ☐Ascending ☐No ☐UK	☐General ☐Ascending ☐No ☐UK	☐General ☐Ascending ☐No ☐UK
If yes, specify P if progressive, give body parts affected	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____
34. Weakness	☐General ☐Focal ☐No ☐UK	☐General ☐Focal ☐No ☐UK	☐General ☐Focal ☐No ☐UK	☐General ☐Focal ☐No ☐UK	☐General ☐Focal ☐No ☐UK	☐General ☐Focal ☐No ☐UK
If yes, specify P if progressive, give body parts affected*	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____	☐P _____ _____ _____ _____ _____ _____
35. Oromotor dysfunction	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
36. Movement disorder	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
37. Shortness of breath	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
38. Sore throat	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
39. Cough	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
40. Rhinitis	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
41. Chest pain	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
42. Back pain	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
43. Myalgia	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
44. Arthralgia	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK

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45. Joint swelling	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
If yes, indicate joints affected	oFingers oToes oKnee oElbow o Other (specify) :_____	oFingers oToes oKnee oElbow o Other (specify) :_____	oFingers oToes oKnee oElbow o Other (specify) :_____	oFingers oToes oKnee oElbow o Other (specify) :_____	oFingers oToes oKnee oElbow o Other (specify) :_____	oFingers oToes oKnee oElbow o Other (specify) :_____
46. Conjunctivitis	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
If yes, specify: P= Purulent or N=non-purulent						
47. Retro-orbital pain	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
48. Periorbital pain	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
49. Rash	☐Centrifugal ☐Centripetal ☐No ☐UK	☐Centrifugal ☐Centripetal ☐No ☐UK	☐Centrifugal ☐Centripetal ☐No ☐UK	☐Centrifugal ☐Centripetal ☐No ☐UK	☐Centrifugal ☐Centripetal ☐No ☐UK	☐Centrifugal ☐Centripetal ☐No ☐UK
If yes, specify type of rash and location:						
50. Pruritus	☐Generalized ☐Localized ☐No ☐UK	☐Generalized ☐Localized ☐No ☐UK	☐Generalized ☐Localized ☐No ☐UK	☐Generalized ☐Localized ☐No ☐UK	☐Generalized ☐Localized ☐No ☐UK	☐Generalized ☐Localized ☐ No ☐UK
51. Jaundice	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
52. Signs of insect bites	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
53. Bleeding	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
If Yes, specify source/onset (e.g. from mucous membranes; gingival; in urine; in feces)	Source: Onset: __/__/20__	Source: Onset: __/__/20__	Source: Onset: __/__/20__	Source: Onset: __/__/20__	Source: Onset: __/__/20__	Source: Onset: __/__/20__
54. Mouth ulcers	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
55. Diarrhea	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
56. Vomiting/nausea	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK
57. Stomach pain	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK	☐Yes ☐No ☐UK

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58. Specify any other signs/symptoms:						
59. Since the last assessment, patient is:	☐Improved ☐Stable ☐Worse	☐Improved ☐Stable ☐Worse	☐Improved ☐Stable ☐Worse	☐Improved ☐Stable ☐Worse	☐Improved ☐Stable ☐Worse	☐Improved ☐Stable ☐Worse

Please also complete the Returning Traveller Laboratory Results CRF (TLR) for all patients.

3) MEDICATIONS AND SUPPORT

60. List medications administered from date of admission: Use generic names. Include antibiotics, antivirals, corticosteroids, immunoglobulin, anticonvulsants, fluids and 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 ☐Topical ☐ Other, detail:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, detail:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, detail:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, detail:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, detail:
						☐IV ☐Oral ☐Rectal ☐Topical ☐ Other, detail:
						☐IV ☐Oral

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						☐Rectal ☐Topical ☐ Other, detail:

4) TRANSFER TO OTHER HOSPITAL (please note that Outcomes are captured in Baseline CRF)

61. Was the patient transferred to another hospital?	☐Yes ☐No ☐Unknown
62. If yes, please state name of the hospital and city (address if possible):	
63. Please state reason for transfer:	

If admitted to intensive care unit, please also complete Returning Traveller Intensive Care CRF (TIC).

5) CASE REPORT COMPLETED BY

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