ZIKA VIRUS CASE REPORT FORMS – RETURNING TRAVELLER BASELINE AND OUTCOME – (TBO)

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 Demographics and Epidemiology 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*.

INCLUSION CRITERIA

Define as appropriate e.g. non-pregnant returning traveller, who has visited a country affected by the current Zika outbreak within 15 days of onset of symptoms.
If pregnant, refer to the ZIKV Maternal and Neonate Case Report forms.

CONSENT

Ensure 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:			
3. City/town/village:			
4. Country:			
5. Date of presentation:	__/__/ 20 __		
6. Admitted to hospital	☐ Yes ☐ No ☐ Unknown		
7. If yes, date of admission (dd/mm/yyyy)	__ / __ / 20 __	**8. Date of discharge**	__ / __ / 20 __ ☐Unknown
9. Name of hospital admitted to and town/city:			
10. Date of onset of first symptoms (dd/mm/yyyy)	__ / __ / 20 __		
If acute symptoms complete the ZIKV Returning Traveller Acute Symptoms (TAS) CRF module as well			

1) DEMOGRAPHICS

11. Gender	☐ Male ☐ Female ☐ Other ☐ Does not wish to say
12. Date of birth (dd/mm/yyyy)	
13. Country of residency	
14. Town/City/Village	
15. Occupation	
16. Ethnicity (according to national guidelines)	

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2) COUNTRIES VISITED (< 15 days of onset of symptoms)

17. State all countries visited within 15 days before date of onset of symptoms				
Country	**City/town/region visited**	**Approximate first and last date [dd/mm/yyyy]**	**Total number of days**	**Includes overnight stay**
		__/__/____ to __/__/____		☐ Yes ☐ No
		__/__/____ to __/__/____		☐ Yes ☐ No
		__/__/____ to __/__/____		☐ Yes ☐ No
		__/__/____ to __/__/____		☐ Yes ☐ No
		__/__/____ to __/__/____		☐ Yes ☐ No
		__/__/____ to __/__/____		☐ Yes ☐ No

3) RISK FACTORS

18. Has the patient received a blood transfusion?	☐Yes ☐No ☐Unknown	**Specify/estimate date of last blood transfusion** ☐<30 days ago ☐>30 days ago	**Reason for transfusion:** _____ _____
19. Does the patient or their partner use any form of sexual protection?	☐YES ☐No ☐Unknown ☐Not applicable	**If yes, which methods?**	o None o Condoms (male/female) o Diaphragm/Cap o Dental dam o Gloves o Other (specify): _____ o Does not wish to say
20. 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:
21. Alcohol consu mption?	☐Yes ☐No ☐Unknown	**If yes, specify average alcohol consumption per day**	**Specify type**_____

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		☐ Less than 1-2 alcoholic drinks[1] per day ☐ 2-5 alcoholic drinks per day ☐ >5 alcoholic drinks per day	

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

4) CO-MORBIDITIES (existing PRIOR TO ADMISSION & which are active problems)

22. Chronic cardiovascular disease[2]	☐Yes ☐No ☐Unknown
23. Chronic pulmonary disease[3]	☐Yes ☐No ☐Unknown
24. Blood disorders	☐Yes ☐No ☐Unknown
If yes, please specify:	
25. Chronic renal/kidney disease[4]	☐Yes ☐No ☐Unknown
26. Chronic liver disease – moderate or severe[5]	☐Yes ☐No ☐Unknown
27. Chronic neurological disease[6]	☐Yes ☐No ☐Unknown
If yes, please specify:	
28. Paralysis	☐Yes ☐No ☐Unknown
If yes, please specify body parts affected:	
29. Type 1 Diabetes	☐Yes ☐No ☐Unknown
30. Type 2 Diabetes and treated with oral medicine or insulin dependent	☐Yes ☐No ☐Unknown
31. Other endocrine disease[7]	☐Yes ☐No ☐Unknown
If yes, please specify:	
32. Rheumatologic disease[8]	☐Yes ☐No ☐Unknown
33. HIV[9]	☐Yes ☐No ☐Unknown
If yes, on antiretroviral therapy?	☐Yes ☐No ☐Unknown
34. CD4 cell count	☐ <200 cells/µL ☐200-499 cells/µL ☐ ≥500 cells/µL ☐Unknown
35. Other immunosuppression?	☐Yes ☐No ☐Unknown

[1] A drink is defined as any alcoholic drink for example a glass of wine, a glass of beer, a cocktail

[2] Includes coronary heart disease, cerebrovascular disease (stroke), hypertension (Diastolic > 100mm/Hg), peripheral artery disease, rheumatic heart disease, congenital heart disease and heart failure. www.who.int/topics/cardiovascular_diseases/en/

[3] Chronic lung diseases that cause limitations in lung airflow (previously referred to as emphysema, chronic bronchitis), diagnosed by spirometry or clinical signs e.g. abnormal shortness of breath and increased forced expiratory time. www.who.int/respiratory/copd/diagnosis/en/

[4] Creatinine >3mg% (265 µmol/l), dialysis, transplantation, uremic syndrome

5 Cirrhosis with PHT +/- variceal bleeding

6 Disorders of the nervous system e.g. epilepsy, MS, Parkinson, chronic pain syndromes, chronic brain injuries, ALS etc.

7 Hypopituitarism, adrenal insufficiency, recurrent acidosis

8 SLE, polymyositis, polymyalgia rheumatic, mixed connective tissue diseases

9 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.

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If yes, please specify:	
36. Any other chronic comorbidity (please specify):	☐Yes ☐No ☐Unknown

5) IMMUNISATION HISTORY

Vaccine	Immunized	Estimate date of last dose (mm/yyyy) or age	Course completed
37. Yellow fever*	☐Yes ☐No ☐Unknown		☐Yes ☐No ☐Unknown
38. Japanese encephalitis*	☐Yes ☐No ☐Unknown		☐Yes ☐No ☐Unknown
39. Tick-borne encephalitis*	☐Yes ☐No ☐Unknown		☐Yes ☐No ☐Unknown
40. Dengue virus	☐Yes ☐No ☐Unknown		☐Yes ☐No ☐Unknown

**These vaccinations may cross-react with ZIKV serology*

6) PREVIOUS ARBOVIRUS INFECTIONS

Arbovirus		Estimated date of onset (mm/yyyy):	Certainty
41. Dengue fever	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
42. Japanese encephalitis	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
43. St. Louis encephalitis	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
44. West Nile virus	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
45. Tick-borne encephalitis	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
46. Chikungunya	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
47. Yellow fever	☐YES ☐NO ☐Unknown	__/____	☐Lab. confirmed ☐Medical records ☐Self-reported
48. Other (specify):		__/____	☐Lab. confirmed ☐Medical records ☐Self-reported

7) BASELINE OBSERVATIONS (≤ 24 hours of admission)

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BASELINE OBSERVATIONS			
49. Date (dd/mm/yyyy)	__ / __ / 20 __ __		
50. Maximum Temperature	_____°C ☐ _____°F ☐ ☐ Unknown ☐Oral ☐Tympanic ☐Axillary ☐Anal ☐Skin		
51. Respiratory Rate	_____breaths/minute ☐ Unknown		
52. Heart Rate	_____ beats/minute ☐ Unknown		
53. Systolic Blood Pressure	_____mmHg ☐ Unknown		
54. Diastolic Blood Pressure	_____mmHg ☐ Unknown		
55. Peripheral O_2 Saturation (SpO_2)	_____ % ☐ Unknown		
56. Glasgow Coma Score (out of 15) or	___ / 15 ☐ Unknown		
57. AVPU (tick state of consciousness)	☐Alert ☐Responds to verbal stimuli ☐ Responds to pain stimuli ☐ Unresponsive		
58. Weight	_____ ☐kg ☐pounds/ounces		
59. Height	_____ ☐cm ☐feet/inches		
60. Weight loss	☐Yes ☐No ☐Unknown		
If yes, specify lost during this current episode of illness	_____ ☐kg ☐pounds/ounces		
61. Lymphadenopathy	☐Cervical only ☐General ☐No ☐Unknown		
62. Enlarged liver	☐ Yes ☐ No ☐ Unknown	**63. Enlarged spleen**	☐Yes ☐No ☐Unknown

8) SYMPTOMS (since first day of onset of this illness episode)

64. Amnesia	☐Yes ☐No ☐Unknown
65. Confusion/disorientation	☐Yes ☐No ☐Unknown
66. Altered behavior or personality	☐Yes ☐No ☐Unknown
67. Headache	☐Mild ☐Moderate ☐Severe ☐No ☐Unknown
68. Photophobia	☐Yes ☐No ☐Unknown
69. Neck stiffness	☐Yes ☐No ☐Unknown
70. Seizures	☐General ☐Focal ☐No ☐Unknown
71. Paralysis	☐General ☐Ascending ☐No ☐Unknown
If yes, please describe affected body parts and if progressive: ☐yes ☐no	
72. Weakness	☐General ☐Focal ☐No ☐Unknown ○Power test ○Patient complaint
If focal, please describe affected body parts and if progressive: ☐yes* ☐no	
73. Oromotor dysfunction	☐Yes ☐No ☐Unknown
74. Movement disorder	☐Yes ☐No ☐Unknown

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75. Shortness of breath	☐Yes ☐No ☐Unknown	
76. Sore throat	☐Yes ☐No ☐Unknown	
77. Cough	☐Yes ☐No ☐Unknown	
78. Rhinitis	☐Yes ☐No ☐Unknown	
79. Chest pain	☐Yes ☐No ☐Unknown	
80. Back pain	☐Yes ☐No ☐Unknown	
81. Myalgia	☐Yes ☐No ☐Unknown	
82. Arthralgia	☐Yes ☐No ☐Unknown	
83. Joint swelling	☐Yes ☐No ☐Unknown	
If yes, specify all affected joints:	○ Fingers ○ Toes ○ Knee ○ Elbow ○ Other (specify):_____	
84. Conjunctivitis	☐Yes ☐No ☐Unknown	
If yes, specify if:	☐Purulent ☐Non-purulent	
85. Retro-orbital pain	☐Yes ☐No ☐Unknown	
86. Periorbital pain	☐Yes ☐No ☐Unknown	
87. Rash	☐Yes ☐No ☐Unknown	
If yes, please check box for type of rash and specify location:		**Spread of the rash:**
88. Maculopapular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
89. Erythematous rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
90. Non blanching rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
91. Vesicular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
92. Erythema migrans	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
93. Pruritic rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
94. Petechial or purpuric rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
95. Bruising/ ecchymosis	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
96. If other type of rash, please specify type and spread:	Type: ○ Face ○ Torso ○ Upper limbs ○ Lower limbs ○ Palms ○ Other:	
97. Pruritus	☐Yes ☐No ☐Unknown	
If yes, specify:	☐ Generalized ☐ Localized	
98. Jaundice	☐Yes ☐No ☐Unknown	
99. Sign of insect bites	☐Yes ☐No ☐Unknown	
100. Bleeding	☐Yes ☐No ☐Unknown	

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If yes, please state source:	○ Bruising ○ Gums ○ Nose ○ Hematemesis ○ Melena or fresh per rectum ○ Hematuria ○ Vaginal ○ Other, specify:
101. Mouth ulcers	☐Yes ☐No ☐Unknown
102. Diarrhea	☐Yes ☐No ☐Unknown
103. Vomiting/nausea	☐Yes ☐No ☐Unknown
104. Stomach pain	☐Yes ☐No ☐Unknown

**** If GBS like symptoms identified, please refer to specific GBS or ZIKV neurological studies.***

9) MEDICATIONS ADMINISTERED (from onset of first symptoms of this illness episode) Please list **all** medications taken by the patient during this episode, including antibiotics, antivirals and other regular medications, including herbal, and non-licensed remedies. Please list generic names if possible.

List all medications administered for acute symptoms:
Use generic names, list all treatment given for this illness episode from date of onset.

Type of medication	**Name of medication and doce** (generic name)	**Start date** (dd/mm/yyyy)	**Number of days duration**	**Route of administration**
105. Antibiotics ☐Yes ☐No				☐IV ☐Oral ☐IM
106. Antivirals ☐Yes ☐No				☐IV ☐Oral
107. Corticosteroids ☐Yes ☐No				☐IV ☐Oral ☐Topical ☐Inhaled
108. Anti-inflammatory or Antipyretic ☐Yes ☐No				☐IV ☐Oral
109. Immunoglobulins ☐Yes ☐No				☐IV ☐Oral ☐ Other, detail:
110. Other (specify):				☐IV ☐Oral ☐ Other, detail:
Other (specify):				☐IV ☐Oral ☐ Other, detail:
Other (specify):				☐IV ☐Oral ☐ Other, detail:
Other (specify):				☐IV ☐Oral ☐ Other, detail:

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10) IMAGING (if available as part of routine care.)

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

Neuroimaging	Results	If abnormal, please summarize key results from report:	Images attached	Report attached
111. CT	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
112. MRI	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
113. EEG	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
114. Other (specify type of test):	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No

11) DIAGNOSTIC OUTCOMES

Record final diagnostics outcomes based on local/regional laboratory results, clinical presentation and case definitions. Please 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	Date of onset (dd/mm/yyyy)	Comment
115. No confirmed diagnosis	☐Tick if no diagnosis made		
116. Zika virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/20__	

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117. Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/20__	
118. Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/20__	
119. West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/20__	
120. Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/20__	
121. Malaria	☐Confirmed acute infection ☐Probable acute infection ☐Negative ☐Not tested ☐Unknown	__/__/20__	
122. Other (specify):	☐Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	__/__/20__	
Other (specify):	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative	__/__/20__	

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12) OUTCOME (Complete at discharge/going home or death)

Outcome	Details
123. Date of discharge/going home [dd/mm/yyyy]	__ / __ / 20__
124. Outcome at discharge/going home	☐Discharged/sent home without sequelae ☐Discharged/ sent home with sequelae ☐Deceased ☐Unknown
125. If discharged/ sent home with sequelae, describe:	
126. If deceased, specify date of death [dd/mm/yyyy]	__ / ___ / _____
127. Zika virus infection	☐Positive ☐Probable ☐Negative ☐Unknown ☐Not tested
128. Diagnosis confirmed by:	☐Lab. confirmed (local hospital laboratory) ☐Lab. confirmed (national reference laboratory) ☐Lab. confirmed (international reference laboratory) ☐Other, please detail: _____
129. Any other outcome, specify all:	
130. Was autopsy performed?	☐Yes ☐No ☐Unknown
If yes, please specify autopsy results:	

13) CASE REPORT COMPLETED BY

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