ZIKA VIRUS CASE REPORT FORMS – ADULT AND CHILD >5YEARS BASELINE AND OUTCOME– (ACBO)

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

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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 (○) 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*.

CONSENT

Ensure each participant (or their parent or guardian if a child) has given *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		
3. If geoposition not available:		
4. City/town/village:		
5. Country:		
6. Admitted to hospital	☐ Yes ☐ No ☐ Unknown *If yes: (also complete form **ACAS**)*	

1) DEMOGRAPHICS

7. Date of Birth [dd/mm/yyyy]	__ / __ / _____
8. Gender	☐ Male ☐ Female
9. Weight	____ ☐ kg ☐ pounds/ounces
10. Height	____ ☐ cm ☐ feet&inches
11. Ethnicity (according to national guidelines)**:**	
12. Occupation	

2) TRAVEL HISTORY (any city, town, village or region visited in the last 4 weeks)

13. Main home address:			
14. Destination travelled to:	**Dates of travel** [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

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

Patient's Identification Code : _______________

3) CHRONIC COMORBIDITIES/PAST MEDICAL HISTORY

15. Chronic cardiovascular disease[1]	☐Yes ☐No ☐Unknown
16. Chronic pulmonary disease[2]	☐Yes ☐No ☐Unknown
17. Blood disorders	☐Yes ☐No ☐Unknown
If yes, specify:	
18. Chronic renal/kidney disease[3]	☐Yes ☐No ☐Unknown
19. Chronic liver disease – moderate or severe[4]	☐Yes ☐No ☐Unknown
20. Chronic neurological disease[5]	☐Yes ☐No ☐Unknown
If yes, specify:	
21. Paralysis (existing prior to this pregnancy)	☐Yes ☐No ☐Unknown
If yes, specify body parts affected:	
22. Type 1 Diabetes	☐Yes ☐No ☐Unknown
23. Type 2 Diabetes and treated with oral medicine or insulin dependent	☐Yes ☐No ☐Unknown
24. Other endocrine disease[6]	☐Yes ☐No ☐Unknown
If yes, specify:	
25. Rheumatologic disease[7]	☐Yes ☐No ☐Unknown
26. Immunosuppression	☐Yes ☐No ☐Unknown
27. HIV[8]	☐Yes ☐No ☐Unknown
If yes, on antiretroviral therapy?	☐Yes ☐No ☐Unknown
28. CD4 cell count	☐ <200 cells/µL ☐ 200-499 cells/µL ☐ ≥500 cells/µL ☐ Unknown
29. Other immunosuppression?	☐Yes ☐No ☐Unknown
If yes, specify:	
30. Any other chronic comorbidity	☐Yes ☐No ☐Unknown
If yes, specify:	

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

[2] 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/

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

4 Cirrhosis with PHT +/- variceal bleeding

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

6 Hypopituitarism, adrenal insufficiency, recurrent acidosis

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

8 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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4) MEDICATION HISTORY

31. Medication history Please list **all** other medications taken by the patient in the 4 weeks before this illness including non-prescription, herbal, and non-licensed remedies. Please list generic names if possible.

Type of medication	**Name of medication** (generic name)	**Dose** (for 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:

5) OTHER RISK FACTORS

32. 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:
33. Alcohol consumption?	☐Yes ☐No ☐Unknown	**If yes, specify average alcohol consumption per day** ☐ Less than 1-2 alcoholic drinks[9] per day ☐ 2-5 alcoholic drinks per day ☐ >5 alcoholic drinks per day	**Specify type:**

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

34. Illicit and recreational drug use?	☐Yes ☐No ☐Unknown	**If yes, specify frequency** ☐ 0-1 occasion per week ☐ 2-5 occasions per week ☐ >5 occasions per week	**Specify all types of drugs used and route of administration:** **Type:** **Route:**
35. Blood transfusion?	☐Yes ☐No ☐Unknown	**Specify/estimate date of last blood transfusion** ☐< 30 days ago ☐>30 days ago	**Reason for transfusion:** ___________________________ ___________________________

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

6) IMMUNIZATION HISTORY

Vaccine	**Immunized**	**Date of last dose** (dd/mm/yyyy)
36. Rubella	☐Yes ☐No ☐Unknown	
37. Measles	☐Yes ☐No ☐Unknown	
38. Mumps	☐Yes ☐No ☐Unknown	
39. Acellular pertussis	☐Yes ☐No ☐Unknown	
40. Varicella	☐Yes ☐No ☐Unknown	
41. Tetanus	☐Yes ☐No ☐Unknown	
42. Diphtheria	☐Yes ☐No ☐Unknown	
43. Polio	☐Yes ☐No ☐Unknown	
44. Seasonal influenza	☐Yes ☐No ☐Unknown	
45. Yellow fever	☐Yes ☐No ☐Unknown	
46. Japanese encephalitis	☐Yes ☐No ☐Unknown	
47. Tick-born encephalitis	☐Yes ☐No ☐Unknown	
48. Dengue virus	☐Yes ☐No ☐Unknown	
49. Hepatitis B	☐Yes ☐No ☐Unknown	
50. Haemophilus influenza type B	☐Yes ☐No ☐Unknown	
51. Meningococcus C	☐Yes ☐No ☐Unknown	
52. Any other vaccinations received	☐Yes ☐No ☐Unknown (if yes, specify immunization type):	
Any other vaccinations received	☐Yes ☐No ☐Unknown (if yes, specify immunization type):	

7) FINAL DIAGNOSIS

Pathogen	**Diagnosis**	**Date of onset** (dd/mm/yyyy)	**Comment**
53. No confirmed diagnosis	☐ Tick if no diagnosis made		
54. Zika virus	☐ Confirmed acute infection ☐Probable acute infection	__/__/____	

	☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown		
55. Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/____	
56. Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/____	
57. West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/____	
58. Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/____	
59. Cytomegalovirus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/____	
60. Herpes Simplex virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/__/____	

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61. Syphilis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	__/ __/ ____	
62. 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	__/ __/ ____	

8) FINAL OUTCOME

Outcome	**Details**
63. Date of discharge/going home [dd/mm/yyyy]	__/ __/ ______
64. Outcome at discharge/going home	☐Discharged/sent home without sequelae ☐Discharged/ sent home with sequelae ☐Deceased ☐Unknown
65. If discharged/ sent home with sequelae, describe:	
66. If deceased, specify date of death [dd/mm/yyyy]	__/ ___/ ________
67. Zika virus infection	☐Positive ☐Probable ☐Negative ☐Unknown ☐Not tested
68. Diagnosis confirmed by	☐Lab. confirmed (local hospital laboratory) ☐Lab. confirmed (national reference laboratory) ☐Lab. confirmed (international reference laboratory) ☐Other, please detail: ______________________________
69. Child: Other outcomes, specify all:	

70. Adult: Other outcomes, specify all:

9) CASE REPORT FORM COMPLETED BY

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