ZIKA VIRUS CASE REPORT FORMS – ADULT AND CHILD >5YEARS HOSPITAL STAY – (ACHS)

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

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

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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: __ __: __ __(hh:mm)
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 admission [dd/mm/yyyy]	___ / ___ / _____	

1) DEMOGRAPHICS

6. Date of Birth [dd/mm/yyyy]	___ / ___ / _____
7. Gender	☐ Male ☐ Female

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3) SYMPTOMS AND VITAL SIGNS (To be completed with the WORST observation in the previous 24 hours)

Study day	Day __	Day __	Day __	Day __
8. Date (dd/mm/yyyy)	____/____/____	____/____/____	____/____/____	____/____/____
9. Time (hh:mm)	____:____	____:___	____:____	____:____
10. Is the patient in a high dependency unit?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, has ACIC form been completed?*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
11. Maximum temperature (°C)	_____	_____	_____	_____
12. Maximum resp. rate (per min.)	_____	_____	_____	_____
13. Maximum heart rate (per min.)	_____	_____	_____	_____
14. Minimum systolic BP (mmHg)	_____	_____	_____	_____
15. Associated diastolic BP (mmHg)	_____	_____	_____	_____
16. Are symptoms recorded on ACAS?*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
17. Is medication recorded on ACAS?*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
18. Are IV fluids recorded on ACAS?*	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable
19. Are laboratory results recorded on ACLR?*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
20. *If this is day of discharge is outcome recorded on ACBO?**	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable
21. Initials of person completing form				

*Please complete a new form **ACIC**, **ACBO**, and **ACAS** for every day of hospital admission, recording NEW symptoms, medications, and IV fluids within the appropriate sections.

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Study day	Day __	Day __	Day __	Day __
Date (dd/mm/yyyy)	____/____/____	____/____/____	____/____/____	____/____/____
Time (hh:mm)	____:____	____:___	____:____	____:____
Is the patient in a high dependency unit?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If yes, has ACIC form been completed?	_____	_____	_____	_____
Maximum temperature (°C)	_____	_____	_____	_____
Maximum resp. rate (per min.)	_____	_____	_____	_____
Maximum heart rate (per min.)	_____	_____	_____	_____
Minimum systolic BP (mmHg)	_____	_____	_____	_____
Associated diastolic BP (mmHg)	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Are symptoms recorded on ACAS?*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Is medication recorded on ACAS?*	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable
Are IV fluids recorded on ACAS?*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Are laboratory results recorded on ACLR?*	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable
If this is day of discharge is outcome recorded on ACBO?*	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable	☐ Yes ☐ No ☐ Not Applicable
Initials of person completing form				

***Please complete a new form **ACIC**, **ACBO**, and **ACAS** for every day of hospital admission, recording NEW symptoms, medications, and IV fluids within the appropriate sections.

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4) SUMMARY: This sheet should be completed for ALL PATIENTS AT THE TIME OF THE FINAL FOLLOW UP VISIT (Day 10-14). If a patient fails to attend daily visits, please try to obtain as much information as possible by telephone.

22. Assessment from: : ☐CRF only ☐ CRF and hospital file ☐CRF and phone

23. Date/time became afebrile (inpatients only)* ___/___/____ (dd/mm/yyyy) ___:___ hh/mm

24. Date and time of final acute illness visit: ___/___/____ (dd/mm/yyyy) ___:___ hh/mm

25. Outcome - Full recovery without complication: ☐ Yes ☐ No

If 'No', insert a code here : [___]

(1 – Incomplete recovery; 2 –Failed to attend follow up; 3 – Transferred; 4 – Death; 5 *– Other (specify)*:

_____

26. Reason for death/transfer: _____

Management:

27. Did the patient receive any IV fluids? ☐ Yes ☐ No

a. If yes, date and time this first occurred: ___/___/____ (dd/mm/yyyy) __:__hh/mm

b. If yes, type of fluid given: _____

28. Did the patient receive any antibiotics? ☐ Yes ☐ No

a. If yes, date and time this first occurred: ___/___/____ (dd/mm/yyyy) __:__hh/mm

b. If yes, which antibiotics: _____

Clinician's final diagnosis:

29. This is a case of Dengue only ☐ Yes ☐ No **/ Chikungunya only** ☐ Yes ☐ No **/ Zika only** ☐ Yes ☐ No

(If 'no', please continue)

a. This is a case of _____ plus another **diagnosis (1):** ☐ Yes ☐ No

If 'yes' specify additional diagnosis 1**:** _____

b. This is a case of _____ plus another **diagnosis (2):** ☐ Yes ☐ No

If 'yes' specify additional diagnosis 2**:** _____

30. This is NOT a case of Dengue/Chikungunya/Zika, but a different main diagnosis: ☐ Yes ☐ No

If 'yes', specify alternative diagnosis**:** _____

31. No final diagnosis can be given: ☐ Yes ☐ No

32. Patient withdrew from the study: ☐ Yes ☐ No

a) If yes, date: ___/___ /____(dd/mm/yyyy)

b) Main reason for withdrawal:_____

CASE REPORT FORM COMPLETED BY

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