



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



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, CONWISE, PREPARE and REACTing to generate standardized clinical and epidemiological research tools. It may be used in conjunction with the following studies: Case control study for microcephaly and congenital ZIKV syndrome; Case-control study for Guillain-Barre syndrome and GBS-like syndrome; Cohort study of pregnant women; Cohort study of newborns of pregnant women with ZIKV; Viral persistence study; ZIKV Seroprevalence study general population; and the Zika Clinical Characterization and Natural history study.

DESIGN OF THIS CASE REPORT FORM (CRF)

This CRF could be used with any of the following set of CRFs: Maternal and Neonate; Child 0-5 year old; Adult and Child >5 and Returning Traveller.

HOW TO USE THIS CRF

When completing the CRF module, 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 should be 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.
- Patients' 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 (neonate and mother) will be collected using all CRF modules as appropriate.

Sites with very low resources or very high patient numbers may select Baseline and Outcome CRF modules and the Epidemiology and Demographics CRF. The decision is up to the site Investigators and study objectives; it may be changed throughout the data collection period. All high quality data is valuable for analysis.

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through patient examination, through 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 (o) 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 keep all of the sheets for each study subject 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, 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 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,*



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

however, there may be issues between Macs and PCs. The PDF format is also available, which should be well formatted on both 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
6. If yes, date of admission (dd/mm/yyyy)	__ / __ / 20 __	7. Date of discharge __ / __ / 20 __ <input type="checkbox"/> Unknown
8. Name of hospital admitted to and town/city:		
9. Date of onset of first symptoms (dd/mm/yyyy)	__ / __ / 20 __	

1) INFORMATION CONCERNING THE PATIENT

10. Date of birth (dd/mm/yyyy)	__ / __ / ____
11. Age	[__ __] <input type="checkbox"/> years <input type="checkbox"/> months <input type="checkbox"/> weeks
12. Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other <input type="checkbox"/> Does not wish to say
13. Pregnant <i>If yes, give Gestational age</i>	<input type="checkbox"/> Yes [__] weeks [__] days <input type="checkbox"/> No
14. Weight	[__ __ __ __] <input type="checkbox"/> kg <input type="checkbox"/> pounds/ounces
15. Height	[__ __ __] <input type="checkbox"/> cm <input type="checkbox"/> inches
16. Maternal Language	
17. Ethnicity (use local classifications)	
18. Parents related?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, specify:
19. Socioeconomic Status (use national guidance or internationally recognized wealth index)	
20. Can you read?	<input type="checkbox"/> Yes <input type="checkbox"/> No
21. Can you write?	<input type="checkbox"/> Yes <input type="checkbox"/> No
22. Education level	<input type="checkbox"/> No schooling (ISCED 01 or 02) <input type="checkbox"/> Some Primary Education (ISCED 03) <input type="checkbox"/> Completed Primary Education (ISCED 1) <input type="checkbox"/> Completed Lower Secondary Education (ISCED 2) <input type="checkbox"/> Completed Upper Secondary Education (ISCED 3) <input type="checkbox"/> Completed Post-Secondary Non-Tertiary Education (ISCED 4) <input type="checkbox"/> Completed Short-Cycle Tertiary Education (ISCED 5)



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

	<input type="checkbox"/> Completed Bachelor's Degree or Equivalent (ISCED 6) <input type="checkbox"/> Completed Master's Degree or Equivalent (ISCED 7) <input type="checkbox"/> Completed Doctoral Degree or Equivalent (ISCED 8)
23. How many other people live in the same house with you?	_____
24. What was the income of each of the residents of your house last month? Please specify person and income in the space provided.	<input type="checkbox"/> Interviewee : _____ <input type="checkbox"/> _____ : _____ <input type="checkbox"/> _____ : _____ <input type="checkbox"/> _____ : _____ <input type="checkbox"/> _____ : _____ <input type="checkbox"/> _____ : _____ Total monthly income : _____ <input type="checkbox"/> Does not know <input type="checkbox"/> Declined to answer
25. Who is the most senior person responsible for your household?	<input type="checkbox"/> Interviewee <input type="checkbox"/> Partner/husband/wife <input type="checkbox"/> Parent <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> No one is responsible for household <input type="checkbox"/> Does not know <input type="checkbox"/> Declined to answer
26. What is the Education level of the most senior person responsible for your household?	<input type="checkbox"/> No schooling (ISCED 01 or 02) <input type="checkbox"/> Some Primary Education (ISCED 03) <input type="checkbox"/> Completed Primary Education (ISCED 1) <input type="checkbox"/> Completed Lower Secondary Education (ISCED 2) <input type="checkbox"/> Completed Upper Secondary Education (ISCED 3) <input type="checkbox"/> Completed Post-Secondary Non-Tertiary Education (ISCED 4) <input type="checkbox"/> Completed Short-Cycle Tertiary Education (ISCED 5) <input type="checkbox"/> Completed Bachelor's Degree or Equivalent (ISCED 6) <input type="checkbox"/> Completed Master's Degree or Equivalent (ISCED 7) <input type="checkbox"/> Completed Doctoral Degree or Equivalent (ISCED 8) Interviewee: <input type="checkbox"/> Does not know <input type="checkbox"/> Declined to answer <input type="checkbox"/> Not applicable
27. Which of the following items are in your household?	<input type="checkbox"/> Dishwasher <input type="checkbox"/> DVD player <input type="checkbox"/> Computer <input type="checkbox"/> Car <input type="checkbox"/> Dryer <input type="checkbox"/> Microwave <input type="checkbox"/> Washer <input type="checkbox"/> Fridge <input type="checkbox"/> Freezer (individual or 2-in-1 freezer/refrigerator)



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

	<input type="radio"/> Motorbike <input type="radio"/> Room with latrine/shower <input type="radio"/> None of the above
28. Does your household employ a paid domestic worker (e.g. cleaner) who is paid on a monthly basis?	<input type="checkbox"/> Yes How many? _____ <input type="checkbox"/> No <input type="checkbox"/> Does not wish to answer
29. Is there a room with a toilet/latrine in your house?	<input type="checkbox"/> Yes, private <input type="checkbox"/> Yes, collective <input type="checkbox"/> No <input type="checkbox"/> Other (specify): _____
30. How is the waste disposed of (choose most common method)	<input type="checkbox"/> Sewage <input type="checkbox"/> Septic tank connected to sewage network <input type="checkbox"/> Septic tank unconnected to sewage network <input type="checkbox"/> Rudimentary tank/cesspit <input type="checkbox"/> Open sewage <input type="checkbox"/> Directly onto water stream/river/sea <input type="checkbox"/> Directly onto water reservoir/lake <input type="checkbox"/> Other (specify): _____
31. Do you live on a paved road?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not wish to answer
32. Have you ever had a job?	<input type="checkbox"/> Yes, currently working <input type="checkbox"/> Yes, was previously working Please give when last employed __/__/____ Please give reason for leaving <input type="checkbox"/> Contract ended <input type="checkbox"/> Pregnancy <input type="checkbox"/> Illness <input type="checkbox"/> Other (specify): _____ <hr style="width: 80%; margin-left: 0;"/> <input type="checkbox"/> Doesn't wish to say <input type="checkbox"/> Never had a job <input type="checkbox"/> Uncertain <input type="checkbox"/> Doesn't wish to say
33. Are you on benefits?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not wish to say
34. Socio-professional category	<input type="checkbox"/> Student <input type="checkbox"/> Farmer <input type="checkbox"/> Artisan, Merchant, Business Owner <input type="checkbox"/> Highly Qualified Professional (Intellectual or Management) <input type="checkbox"/> Intermediate professions (<i>see completion guidelines</i>) <input type="checkbox"/> Employee <input type="checkbox"/> Laborer/Factory Worker



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

	<input type="checkbox"/> Without Profession <input type="checkbox"/> Retired <input type="checkbox"/> Not disclosed <input type="checkbox"/> Child not in Education
35. Where (city/municipality) do/did you work?	_____
36. Have you ever been exposed to these items while at work?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Do not wish to say <input type="checkbox"/> NA – never worked If yes, tick all that apply <input type="radio"/> Agrotoxics <input type="radio"/> Ink/paint <input type="radio"/> Solvent <input type="radio"/> Rat poison <input type="radio"/> Scorpion poison <input type="radio"/> Cockroach poison <input type="radio"/> Other chemical product (specify): _____

2) ZIKA CONTACTS

37. Has anyone you know had Zika infection? If yes (give date of presentation to clinic) : <input type="radio"/> Partner <input type="radio"/> Children <input type="radio"/> Parent <input type="radio"/> Neighbors <input type="radio"/> Close friend/relative <input type="radio"/> Other (specify): _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Date of presentation to clinic: ___/___/___ ___/___/___ ___/___/___ ___/___/___ ___/___/___ ___/___/___
38. Have you had sexual contact with anyone who has recently travelled to a Zika infected area (i.e. within the last 6 months)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Does not wish to answer	
39. Within the last 4 weeks: please state number of partners and sex of partners	___ Male ___ Female ___ Does not wish to say	
40. Within the last 4 weeks: please state number of times sexual activity has occurred	_____	
41. Within the last 4 weeks: please specify types of sexual activity undertaken (tick all that apply)	<input type="radio"/> Oral <input type="radio"/> Vaginal <input type="radio"/> Anal <input type="radio"/> Other (specify): _____ <input type="radio"/> Does not wish to say	



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

42. Within the last 4 weeks: please specify types of protection used (tick all that apply)	<input type="radio"/> None <input type="radio"/> Condoms (male/female) <input type="radio"/> Diaphragm/Cap <input type="radio"/> Dental dam <input type="radio"/> Gloves <input type="radio"/> Other (specify): _____ <input type="radio"/> Does not wish to say
---	--

3) ENVIRONMENTAL FACTORS

43. Type of Residence	<input type="checkbox"/> Apartment <input type="checkbox"/> House <input type="checkbox"/> Other (specify): _____
44. Location of Residence	<input type="checkbox"/> City/urban <input type="checkbox"/> Rural/countryside <input type="checkbox"/> Other (specify): _____
45. Protection Against Mosquito Bites	<input type="radio"/> Long Pants/Sleeves If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Mosquito Net If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Essential Oils If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Mosquito Repellant Spray If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Other (specify): _____ If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often
46. Vector Control	<input type="radio"/> Insecticides for Larvae If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Removing Standing Water from Around House If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Insecticide Fogging If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often <input type="radio"/> Other (specify): _____ If yes, <input type="checkbox"/> Daily <input type="checkbox"/> Sometimes <input type="checkbox"/> Often



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

4) TRAVEL HISTORY (any city, town, village or region visited in the last 4 weeks, if pregnant, give any travel for duration of pregnancy)

Please include any additional information not previously filled out in other CRFs, please do not repeat.

47. Any history of travel (local/national/international) <input type="checkbox"/> Yes <input type="checkbox"/> No	Approximate first and last date [dd/mm/yyyy]	Total number of days	Includes overnight stay
48. Main home address: _____	__/__/__ to __/__/__		<input type="checkbox"/> Yes <input type="checkbox"/> No
49. If yes: Other places visited:	__/__/__ to __/__/__		<input type="checkbox"/> Yes <input type="checkbox"/> No
	__/__/__ to __/__/__		<input type="checkbox"/> Yes <input type="checkbox"/> No
	__/__/__ to __/__/__		<input type="checkbox"/> Yes <input type="checkbox"/> No
	__/__/__ to __/__/__		<input type="checkbox"/> Yes <input type="checkbox"/> No
	__/__/__ to __/__/__		<input type="checkbox"/> Yes <input type="checkbox"/> No

5) OTHER RISK FACTORS

Please include any additional information not previously filled out in other CRFs, please do not repeat

50. Tobacco use?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If yes, specify average per day: <input type="checkbox"/> <10 cigarettes per day <input type="checkbox"/> ≥10 cigarettes per day	<input type="checkbox"/> Other forms of smoking/tobacco Specify: _____
51. Alcohol consumption?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If yes, specify average alcohol consumption per day <input type="checkbox"/> Less than 1-2 alcoholic drinks ¹ per day <input type="checkbox"/> 2-5 alcoholic drinks per day <input type="checkbox"/> >5 alcoholic drinks per day	Specify type _____
52. Illicit and recreational drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If yes, specify frequency <input type="checkbox"/> 0-1 occasion per week <input type="checkbox"/> 2-5 occasions per week <input type="checkbox"/> >5 occasions per week	Specify all types of drugs used and route of administration: Type: Route:
53. Have you ever received a blood transfusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Specify/estimate date of last blood transfusion <input type="checkbox"/> < 30 days ago <input type="checkbox"/> >30 days ago	Reason for transfusion: _____ _____

¹ A drink is defined as any alcoholic drink for example a glass of wine, a glass of beer, a cocktail
ZIKV CRF Epidemiology and Demographics v4.1 07DEC2016



ZIKA VIRUS CASE REPORT FORMS – EPIDEMIOLOGY AND DEMOGRAPHICS – (EPI&DEMO)



Patient's Identification Code : _____

54. Have you ever donated blood?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Date of last donation: __/__/____	
55. Have you ever received an organ donation?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Date last organ received: __/__/____	Organ received: _____
56. Have you ever donated an organ?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not wish to say	Date of last donation: __/__/____	Organ donated: _____

5) CASE REPORT FORM COMPLETED BY

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