***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. 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 (**○**) 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, 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: \_\_\_\_. \_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 1. **Name of site/clinic/hospital**
 |  |
| **If geoposition not available:**  |
| 1. **City/town/village**
 |  |
| 1. **Country**
 |  |
| 1. **Admitted to hospital**
 | **☐** Yes  **☐** No **☐** Unknown |
| 1. **If yes, date of admission** (dd/mm/yyyy)
 | \_\_ / \_\_ / 20 \_\_ | 1. **Date of discharge**
 | \_\_ / \_\_ / 20 \_\_ **☐**Unknown  |
| 1. **Name of hospital admitted to and town/city:**
 |  |
| 1. **Date of onset of first symptoms** (dd/mm/yyyy)
 | \_\_ / \_\_ / 20 \_\_ |

# 1) INFORMATION CONCERNING THE PATIENT

|  |  |
| --- | --- |
| 1. **Date of birth** (dd/mm/yyyy)
 | \_\_/\_\_/\_\_\_\_ |
| 1. **Age**
 | [\_\_|\_\_|] ☐ years ☐ months ☐ weeks |
| 1. **Gender**
 | **☐** Male **☐** Female  **☐** Other **☐** Does not wish to say |
| 1. **Pregnant**

***If yes, give Gestational age*** | **☐** Yes  [\_\_] weeks [\_\_] days **☐** No |
| 1. **Weight**
 | [\_\_|\_\_|\_\_|\_\_] **☐** kg **☐** pounds/ounces |
| 1. **Height**
 | [\_\_|\_\_|\_\_] **☐** cm **☐** inches |
| 1. **Maternal Language**
 |  |
| 1. **Ethnicity (use local classifications)**
 |  |
| 1. **Parents related?**
 | **☐** Yes **☐** No If yes, specify: |
| 1. **Socioeconomic Status**

**(use national guidance or internationally recognized wealth index)** |  |
| 1. **Can you read?**
 | **☐** Yes **☐** No |
| 1. **Can you write?**
 | **☐** Yes **☐** No |
| 1. **Education level**
 | **☐** No schooling (ISCED 01 or 02)**☐** Some Primary Education (ISCED 03)**☐** Completed Primary Education (ISCED 1)**☐** Completed Lower Secondary Education (ISCED 2)**☐** Completed Upper Secondary Education (ISCED 3)**☐** Completed Post-Secondary Non-Tertiary Education (ISCED 4)**☐** Completed Short-Cycle Tertiary Education (ISCED 5)**☐** Completed Bachelor's Degree or Equivalent (ISCED 6)**☐** Completed Master's Degree or Equivalent (ISCED 7)**☐** Completed Doctoral Degree or Equivalent (ISCED 8) |
| 1. **How many other people live in the same house with you?**
 | \_\_\_\_\_ |
| 1. **What was the income of each of the residents of your house last month? Please specify person and income in the space provided.**
 | **☐** Interviewee : \_\_\_\_\_\_\_\_\_\_\_**☐** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ : \_\_\_\_\_\_\_\_\_\_\_**☐** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ : \_\_\_\_\_\_\_\_\_\_\_**☐** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ : \_\_\_\_\_\_\_\_\_\_\_**☐** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ : \_\_\_\_\_\_\_\_\_\_\_**☐** \_\_\_\_\_\_\_\_\_\_\_\_\_\_ : \_\_\_\_\_\_\_\_\_\_\_ Total monthly income : \_\_\_\_\_\_\_\_\_\_\_**☐** Does not know**☐** Declined to answer |
| 1. **Who is the most senior person responsible for your household?**
 | **☐** Interviewee**☐** Partner/husband/wife**☐** Parent**☐** Other (specify): \_\_\_\_\_\_\_\_\_**☐** No one is responsible for household**☐** Does not know**☐** Declined to answer |
| 1. **What is the Education level of the most senior person responsible for your household?**
 | **☐** No schooling (ISCED 01 or 02)**☐** Some Primary Education (ISCED 03)**☐** Completed Primary Education (ISCED 1)**☐** Completed Lower Secondary Education (ISCED 2)**☐** Completed Upper Secondary Education (ISCED 3)**☐** Completed Post-Secondary Non-Tertiary Education (ISCED 4)**☐** Completed Short-Cycle Tertiary Education (ISCED 5)**☐** Completed Bachelor's Degree or Equivalent (ISCED 6)**☐** Completed Master's Degree or Equivalent (ISCED 7)**☐** Completed Doctoral Degree or Equivalent (ISCED 8)Interviewee:**☐** Does not know  **☐** Declined to answer  **☐** Not applicable |
| 1. **Which of the following items are in your household?**
 | **○** Dishwasher**○** DVD player**○** Computer**○** Car**○** Dryer**○** Microwave**○** Washer**○** Fridge**○** Freezer (individual or 2-in-1 freezer/refrigerator)**○** Motorbike**○** Room with latrine/shower**○** None of the above |
| 1. **Does your household employ a paid domestic worker (e.g. cleaner) who is paid on a monthly basis?**
 | **☐** Yes  How many? \_\_\_\_\_ **☐** No**☐** Does not wish to answer |
| 1. **Is there a room with a toilet/latrine in your house?**
 | **☐** Yes, private**☐** Yes, collective**☐** No**☐** Other (specify): \_\_\_\_\_\_\_\_ |
| 1. **How is the waste disposed of (choose most common method)**
 | **☐** Sewage**☐** Septic tank connected to sewage network**☐** Septic tank unconnected to sewage network**☐** Rudimentary tank/cesspit**☐** Open sewage**☐** Directly onto water stream/river/sea**☐** Directly onto water reservoir/lake**☐** Other (specify): \_\_\_\_\_\_\_\_ |
| 1. **Do you live on a paved road?**
 | **☐** Yes **☐** No **☐** Does not wish to answer |
| 1. **Have you ever had a job?**
 | **☐** Yes, currently working**☐** Yes, was previously working Please give when last employed \_\_/\_\_/\_\_\_\_ Please give reason for leaving **☐** Contract ended **☐** Pregnancy **☐** Illness  **☐** Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **☐** Doesn't wish to say**☐** Never had a job**☐** Uncertain **☐** Doesn't wish to say  |
| 1. **Are you on benefits?**
 | **☐** Yes **☐** No **☐** Does not wish to say |
| 1. **Socio-professional category**
 | **☐** Student**☐** Farmer**☐** Artisan, Merchant, Business Owner**☐** Highly Qualified Professional (Intellectual or Management)**☐** Intermediate professions (*see completion guidelines*)**☐** Employee**☐** Laborer/Factory Worker**☐** Without Profession**☐** Retired**☐** Not disclosed**☐** Child not in Education |
| 1. **Where (city/municipality) do/did you work?**
 |  |
| 1. **Have you ever been exposed to these items while at work?**
 | **☐** Yes **☐** No **☐** Don’t know **☐** Do not wish to say **☐** NA – never worked If yes, tick all that apply**○** Agrotoxics**○** Ink/paint**○** Solvent**○** Rat poison**○** Scorpion poison**○** Cockroach poison**○** Other chemical product (specify): \_\_\_\_\_\_\_\_\_ |

# 2) ZIKA CONTACTS

|  |  |  |
| --- | --- | --- |
| 1. **Has anyone you know had Zika infection?**

**If yes (give date of presentation to clinic) :****○ Partner****○ Children****○ Parent****○ Neighbors****○ Close friend/relative****○ Other (specify): \_\_\_\_\_\_** | **☐** Yes **☐** No **☐** Unknown**☐** Yes **☐** No **☐** Unknown**☐** Yes **☐** No **☐** Unknown**☐** Yes **☐** No **☐** Unknown**☐** Yes **☐** No **☐** Unknown**☐** Yes **☐** No **☐** Unknown**☐** Yes **☐** No **☐** Unknown | Date of presentation to clinic:\_\_ / \_\_ / \_\_\_\_\_\_\_ / \_\_ / \_\_\_\_\_\_\_ / \_\_ / \_\_\_\_\_\_\_ / \_\_ / \_\_\_\_\_\_\_ / \_\_ / \_\_\_\_\_\_\_ / \_\_ / \_\_\_\_\_ |
| 1. **Have you had sexual contact with anyone who has recently travelled to a Zika infected area (i.e. within the last 6 months)?**
 | **☐** Yes **☐** No **☐** Unknown**☐** Does not wish to answer |
| 1. **Within the last 4 weeks: please state number of partners and sex of partners**
 | \_\_\_Male \_\_\_Female \_\_\_Does not wish to say |
| 1. **Within the last 4 weeks: please state number of times sexual activity has occurred**
 | \_\_\_\_\_\_\_\_ |
| 1. **Within the last 4 weeks: please specify types of sexual activity undertaken (tick all that apply)**
 | **○** Oral**○** Vaginal**○** Anal**○** Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**○** Does not wish to say |
| 1. **Within the last 4 weeks: please specify types of protection used (tick all that apply)**
 | **○** None**○** Condoms (male/female)**○** Diaphragm/Cap**○** Dental dam**○** Gloves**○** Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**○** Does not wish to say |

# 3) ENVIRONMENTAL FACTORS

|  |  |
| --- | --- |
| 1. **Type of Residence**
 | **☐** Apartment**☐** House**☐** Other (specify): \_\_\_\_\_\_\_\_\_ |
| 1. **Location of Residence**
 | **☐** City/urban**☐** Rural/countryside**☐** Other (specify): \_\_\_\_\_\_\_\_\_ |
| 1. **Protection Against Mosquito Bites**
 | **○** Long Pants/SleevesIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Mosquito NetIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Essential OilsIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Mosquito Repellant SprayIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Other (specify): \_\_\_\_\_\_\_\_\_If yes, **☐** Daily **☐** Sometimes **☐** Often |
| 1. **Vector Control**
 | **○** Insecticides for LarvaeIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Removing Standing Water from Around HouseIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Insecticide FoggingIf yes, **☐** Daily **☐** Sometimes **☐** Often**○** Other (specify): \_\_\_\_\_\_\_If yes, **☐** Daily **☐** Sometimes **☐** Often |

# 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.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Any history of travel (local/national/international)**

**☐ Yes ☐ No** | **Approximate first and last date [dd/mm/yyyy]** | **Total number of days** | **Includes overnight stay** |
| 1. **Main home address:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
| 1. ***If yes:* Other places visited:**
 | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |
|  | \_\_/\_\_/\_\_\_\_ to \_\_/\_\_/\_\_\_\_ |  | **☐** Yes **☐** No |

# 5) OTHER RISK FACTORS

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

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Tobacco use?**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify average per day:****☐** <10 cigarettes per day**☐** ≥10 cigarettes per day | **☐** Other forms of smoking/tobaccoSpecify: |
| 1. **Alcohol consumption?**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify average alcohol consumption per day****☐** Less than 1-2 alcoholic drinks[[1]](#footnote-1) per day**☐** 2-5 alcoholic drinks per day**☐** >5 alcoholic drinks per day | **Specify type\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 1. **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:** |
| 1. **Have you ever received a blood transfusion?**
 | **☐**Yes**☐**No **☐**Unknown | **Specify/estimate date of last blood transfusion** **☐**< 30 days ago**☐**>30 days ago | **Reason for transfusion:****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  |
| 1. **Have you ever donated blood?**
 | ☐ Yes☐ No☐ Unknown | Date of last donation: \_\_/\_\_/\_\_\_\_ |
| 1. **Have you ever received an organ donation?**
 | ☐ Yes☐ No☐ Unknown | Date last organ received:\_\_/\_\_/\_\_\_\_ | Organ received:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Have you ever donated an organ?**
 | ☐ Yes☐ No☐ 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) |  |

1. A drink is defined as any alcoholic drink for example a glass of wine, a glass of beer, a cocktail [↑](#footnote-ref-1)