***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.

***DESIGN OF THIS CASE REPORT FORM (CRF)***

There are two sets of Case Report Form (CRF) to be used - Neonate and Maternal. The CRFs are 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 **Maternal Baseline and Outcome (MBO)** and **Neonate Baseline and Outcome (NBO)** CRFs, follow by **Maternal Laboratory Results (MLR)** and **Neonate Laboratory Results (NLR)** CRFs for all neonates post-delivery. If the mother and/or neonate is admitted to an Intensive Care Unit or Pediatric Intensive Care Unit, complete **Maternal Intensive Care (MIC)**, and/or **Neonate Intensive Care (NIC)** as well.

For pregnant women presenting with acute symptoms, complete **Maternal Acute Symptoms (MAS)**, and for all studies complete **Maternal Antenatal Care (MAC).**

Complete the outcomes sections in CRFs **MBO** and **NBO** 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 mother 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 both mother/pregnant woman and neonate 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 **Maternal and Neonatal Baseline and Outcome** CRF modules. The decision is up to the Site Investigators and may be changed throughout the data collection period. All high quality data is valuable for analysis.

**GENERAL GUIDANCE**

* The CRFs are designed to collect data obtained through patient examination, through parent/guardian/representative (for neonates) interview and review of hospital notes.
* Patient ID codes should be filled in on all pages of paper CRF forms (neonate and mother).
* 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.*

**INCLUSION CRITERIA**

**Define as appropriate for each study and as per latest national guidelines.**

**CONSENT**

**Ensure informed consent.**

|  |
| --- |
| **Date and time of consent** (dd/mm/yyyy): \_\_ \_\_ / \_\_ \_\_ / 20 \_\_ \_\_ Time: \_\_ \_\_: \_\_ \_\_(hours:min) |
| **Name and role of the person taking consent** : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| **Signature of person taking consent**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

|  |  |
| --- | --- |
| 1. **Name of site/clinic/hospital**
 |  |
| 1. **Geoposition**
 | **Latitude:\_\_\_ . \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Longitude: \_\_\_ . \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **If geoposition not available, state location below** |
| 1. **City/town/village:**
 |  |
| 1. **Country (& region/district):**
 |  |

**1) NEONATE DEMOGRAPHICS**

|  |  |
| --- | --- |
| 1. **Sex**
 |  **☐**Male **☐**Female **☐**Uncertain  |
| 1. **Date of birth** (dd/mm/yyyy)
 | \_\_\_\_ / \_\_\_\_ / 20 \_\_\_\_ |
| 1. **Gestational age at birth**
 | \_\_\_\_ weeks \_\_\_\_ days  |
| 1. **Basis of gestational age estimation at birth**
 | **☐**Last menstrual period **☐**Ultrasound **☐**Assisted reproduction**☐**Other (specify): |
| 1. **Birth number**
 | **☐**Singleton **☐**Twin I **☐**Twin II **☐**Triplet I **☐**Triplet II **☐**Triplet III **☐**Other: \_\_\_\_\_\_  |
| 1. **Ethnicity of baby** (as per national guidelines):
 |   |
| 1. **Fetal presentation at delivery**
 | **☐**Cephalic **☐**Breech **☐**Other (specify): |

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

**2) NEONATE MEASUREMENTS AT BIRTH**

 **\*Head circumference to be TAKEN <12 HOURS AFTER BIRTH, AND NO LATER THAN 24 HOURS.**

|  |  |
| --- | --- |
| 1. **Apgar scores**

**☐** Yes **☐** Not done If yes give scores | \_\_\_\_ 1min \_\_\_\_ 5min \_\_\_\_ 10min |
| 1. **Birth weight** (<12 hrs after delivery)

**☐** Yes **☐** Not done If yes give measurements |  \_\_\_\_ | grams |  \_\_\_\_ | pounds |  \_\_\_\_ | ounces |
| 1. **Crown-to-heel length**

**☐** Yes **☐** Not done If yes give measurements |  \_\_\_\_ | cm |  \_\_\_\_ | inches |  |
| 1. **Head circumference \***(occipito-frontal)

**☐** Yes **☐** Not done If yes give measurements |  \_\_\_\_ |  cm |  \_\_\_\_ | inches |  |
| Plot metrics in growth curve as per your national guidelines and record the standard deviations above (indicated with “+”) or below (indicated with “-”) the mean for age and sex | 1. **Birth weight**

\_\_\_\_SD | 1. **Crown-to-heel length**

\_\_\_\_ SD | 1. **Head circumference**

\_\_\_\_ SD |
| 1. **Mother’s head circumference**

**☐** Yes **☐** Not done If yes give measurements |  \_\_\_\_ | cm |  \_\_\_\_ | inches |  |
| 1. **Father’s head circumference**

**☐** Yes **☐** Not done If yes give measurements |  \_\_\_\_ | cm |  \_\_\_\_ | inches |  |

**3) BIRTH ABNORMALITIES**

**Please complete this section in full even if no abnormalities were present**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Fontanelle present**
 | **Anterior:** **☐**Yes **☐**No **☐**Unknown  | **Posterior:** **☐**Yes **☐**No **☐**Unknown  | **Bulging:****☐**Yes **☐**No **☐**Unknown  |
| 1. **Abnormal skull shape**
 | **☐**Yes **☐**No **☐**Unknown  | **☐** Oxicefalia **☐** Plagiocefalia **☐** Trigocefalia **☐** Escafocefalia **☐** Acrocefalia  |
|  **If yes, circle most appropriate depiction[[1]](#footnote-1):** |
| 1. **Sloping forehead**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:**  |
| 1. **Craniosynostosis**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:**  |
| 1. **Cephalohematoma**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:**  |
| 1. **Subgaleal hemorrhage**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:**  |
| 1. **Redundant skin on skull at birth**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:**  |
| 1. **Facial disproportion**
 | **☐**Yes **☐**No **☐**Unknown  | **If yes, specify/describe:** |
| 1. **Nasal abnormalities**
2. **Flat nasal bridge**
3. **Anteverted nares**
4. **Other nasal abnormalities**
 | **☐**Yes **☐**No **☐**Unknown **☐**Yes **☐**No **☐**Unknown **☐**Yes **☐**No **☐**Unknown **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:** |
| 1. **Orofacial clefts**
 | **☐**Yes **☐**No **☐**Unknown**☐** Cleft lip **☐** Cleft palate **☐** Both  | **☐**left **☐**right **☐**middle **☐**bilateral  |
| 1. **Eye abnormalities**
 | **☐**Yes **☐**No **☐**Unknown**☐**Anophthalmia **☐**Microphthalmia  | **☐ Other (describe):** |
| 1. **Ear abnormalities**
 | **☐**Yes **☐**No **☐**Unknown**☐** Anotia (absent ear/s) **☐** Microtia (small ear/s)  | **☐ Other (describe):** |
| 1. **Hemangiomas**
 | **☐** Present **☐** Absent | **○** Facial **○** Rest of body  Number of them:\_\_\_\_\_ |
| 1. **Neural tube defects**
 | **☐**Yes **☐**No **☐**Unknown **☐** Spina bifida **☐** Meningocele**☐** Anencephaly  | **☐ Other (describe):** |
| 1. **Scoliosis**
2. **Barrel-like chest**
 | **☐**Yes **☐**No **☐**Unknown**☐**Yes **☐**No **☐**Unknown  |  |
| 1. **Upper Limb abnormalities**

**If yes, specify/describe:** | **☐**Yes **☐**No **☐**UnknownArthrogryposis **☐**Yes **☐**NoAmyoplasia **☐**Yes **☐**NoIf yes: **☐**Distal **☐**SyndromicHyperextension **☐**Yes **☐**NoIf yes, indicate joints: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Contractures **☐**Yes **☐**NoIf yes, indicate joints: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **☐Other (describe):** |
| 1. **Hand abnormalities**

**If yes, specify/describe:** | **☐**Yes **☐**No **☐**Unknown**○** Clinodactyly **☐** Unilateral **☐** Bilateral**○** Missing digits **☐** Unilateral **☐** Bilateral**○** Extra digits**☐** Unilateral **☐** Bilateral**○** Camptodactyly **☐** Unilateral **☐** Bilateral**○** Nail hypoplasia/aplasia**○** Adducted thumb **○** Bilateral simian crease | **☐Other (describe):** |
| 1. **Lower Limb abnormalities**

**If yes, specify/describe:** | **☐**Yes **☐**No **☐**UnknownArthrogryposis **☐**Yes **☐**NoAmyoplasia **☐**Yes **☐**NoIf yes: **☐**Distal **☐**SyndromicHyperextension **☐**Yes **☐**NoIf yes, indicate joints): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Joint dislocation/subluxation **☐**Yes **☐**NoIf yes, indicate joints): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Contractures **☐**Yes **☐**NoIf yes, indicate joints): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **☐Other (describe):** |
| 1. **Feet abnormalities**

**If yes, specify/describe:** | **☐**Yes **☐**No **☐**Unknown**○** Widely spaced toes**☐** Unilateral **☐**Bilateral**○** Missing toes **☐** Unilateral **☐**Bilateral**○** Extra toes**☐** Unilateral **☐**Bilateral**○** Clubfoot**☐** Unilateral **☐**Bilateral**○** Nail**☐** Unilateral **☐**Bilateral | **☐Other (describe):** |
| 1. **Umbilical hernia**
 | **☐** Present **☐** Absent |  |
| 1. **Gastroschisis**
 | **☐**Yes **☐**No **☐**Unknown  |  |
| 1. **Omphalocele**
 | **☐**Yes **☐**No **☐**Unknown  |  |
| 1. **Any other significant abnormalities present**

**If yes, specify/describe:** | **☐**Yes **☐**No **☐**Unknown **Cardiac: ☐**Yes **☐**No **☐**Unknown **Renal: ☐**Yes **☐**No **☐**Unknown **Organomegaly (enlarged liver/spleen)****☐**Yes **☐**No **☐**Unknown  | **☐Other (describe):** |
| 1. **Down’s syndrome features**
 | **☐**Yes **☐**No **☐**Unknown  |  |
| 1. **Known familial genetic disorders**
 | **☐**Yes **☐**No **☐**Unknown  | **If yes, please specify:** |
| 1. **Other Syndromic abnormalities identified by Physician**
 | **☐**Yes **☐**No **☐**Unknown  | **If yes, please specify:** |

**4) OTHER TEST AND/OR EXAMINATION**

|  |  |  |
| --- | --- | --- |
| **Test** | **Result** | **If abnormal, please describe abnormality:** |
| 1. **Fundoscopy**
 | **☐**Normal **☐**Abnormal **☐**Not Done |  |
| 1. **Red reflex**
 | **☐**Present **☐**Absent **☐**Not Done  |  |
| 1. **Cataract**
 | **☐**Normal **☐**Abnormal **☐**Not Done |  |
| 1. **Chorioretinitis**
 | **☐** Absent **☐** Present **☐** Examination Not Done |  |
| 1. **Hearing test**
 | **☐**Normal **☐**Abnormal **☐**Not Done | **Specify test used:** |
| 1. **Congenital heart defects**
 | **☐**Yes **☐**No **☐**Unknown  | **If yes, specify:** |
| 1. **Any other significant findings**
 | **☐**Yes **☐**No  | **If yes, specify:** |
| **Newborn blood screening** | 1. **Hypothyroidism**

**☐**Negative **☐**Positive **☐**Not Done | 1. **Phenylketonuria**

**☐**Negative **☐**Positive **☐**Not Done | 1. **Other (specify):**

**☐**Negative **☐**Positive  |

**5) BASELINE OBSERVATIONS DAY 0 (≤ 24 hours post-delivery)**

*\*If a neuromuscular and/or neurodevelopmental assessment is required within the first 24hrs, please complete the additional gestational assessment using the Neurological Examination indicated as per your hospital guidelines and protocol.*

|  |  |
| --- | --- |
| 1. **Date** (dd/mm/yyyy)
 | \_\_ \_\_ / \_\_ \_\_ / 20 \_\_ \_\_ |
| **General physical examination** |
| 1. **Maximum temperature**
 | \_\_\_\_.\_\_°C or \_\_\_\_\_ Fahrenheit**☐**Oral **☐**Tympanic **☐**Axillary **☐**Anal **☐**Skin**☐**Other (specify): |
| 1. **Respiratory rate**
 |  | breaths/minute **☐** Not done |
| 1. **Heart rate**
 |  | beats/minute **☐** Not done |
| 1. **Capillary refill time (central)**
 |  | Seconds **☐** Not done |
| 1. **Peripheral O2 saturation (SpO2)**
 |  | % **☐** Not done |
| 1. **Cardiovascular system**
 | **☐**Normal **☐**Abnormal **☐**Unknown | **☐**Murmur **☐**Other (specify) : |
| 1. **Respiratory system**
 | **☐**Normal **☐**Abnormal **☐**Unknown | If abnormal, describe: |
| 1. **Gastrointestinal system**
 | **☐**Normal **☐**Abnormal **☐**Unknown | **☐**Jaundice **☐**Abdominal tenderness **☐**Hepatomegaly **☐**Splenomegaly **☐**Other (specify): |
| 1. **Edema**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, describe affected parts:** |
| 1. **Cryptorchidism**
 | **☐**Yes **☐**No **☐**Unknown**☐** Not applicable  |  |
| 1. **Type of cry**
 | **☐**Strong normal cry **☐**Weak, high-pitched or continuous cry **☐**Not crying **☐**Other: |
| **Neurological examination** |
| 1. **Tonic neck reflex**
 | **☐** Symmetrical **☐** Asymmetrical **☐**Absent **☐**Not Done |
| 1. **Sucking reflex**
 | **☐** Present **☐** Absent |
| 1. **Grasp reflex**
 | **Left foot ☐** Present **☐** Absent | **Right foot ☐** Present **☐** Absent |
| **Left hand ☐** Present **☐** Absent | **Right hand ☐** Present **☐** Absent |
| 1. **Moro reflex**
 | **☐**Present **☐**Absent **☐**Not Done | **☐**Symmetrical **☐**Asymmetrical  |
| 1. **Rooting reflex**
 | **☐**Present **☐**Absent **☐**Not Done |  |
| 1. **Deep tendon reflexes**
 | **Biceps** | **Left****☐**Present **☐**Absent **☐**Not Done | **Right** **☐**Present **☐**Absent**☐**Not Done |
|  | **Brachioradialis** | **☐**Present **☐**Absent **☐**Not Done | **☐**Present **☐**Absent**☐**Not Done |
|  | **Triceps**  | **☐**Present **☐**Absent **☐**Not Done | **☐**Present **☐**Absent**☐**Not Done |
|  | **Patellar**  | **☐**Present **☐**Absent **☐**Not Done | **☐**Present **☐**Absent**☐**Not Done |
|  | **Achilles tendon** | **☐**Present **☐**Absent **☐**Not Done | **☐**Present **☐**Absent**☐**Not Done |
| 1. **Muscle tone**
 | **☐**Normal **☐**Hypertonic **☐**Hypotonic  | If hypertonic, specify which limbs involved:  |
| 1. **Extremity movements**
 | **☐**Symmetrical **☐**Asymmetrical **☐**Unknown |
| 1. **Seizure(s)**
 | **☐**General **☐**Focal **☐**No **☐**Unknown | Fever-associated: **☐**Yes **☐**No **☐**Unknown |
| **If seizures are present, describe:**Frequency: \_ \_ times per **☐** Hour **☐** Day **☐** Week **☐** Month Average length: \_ \_ **☐** Seconds **☐** Minutes **☐** Hours **☐** Continuous **☐**Other (specify): |
| 1. **Paralysis**
 | **☐**General **☐**Ascending **☐**No **☐**Unknown | **If yes, describe:** |
| 1. **Contractures**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, describe:** |
| 1. **Other neurological signs\***
 | **☐**Yes **☐**No  | **If yes, describe:** |
| 1. **Other abnormal movements\* e.g. writhing movements**
 | **☐**Yes **☐**No  | **If yes, describe:** |
| **Skin abnormalities** |
| 1. **Rash**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, date of rash onset** (dd/mm/yyyy) | **\_\_ \_\_ / \_\_ \_\_ / 20 \_\_ \_\_** |
| If yes, describe type of rash  | **Body distribution of rash** |
| 1. **Maculopapular rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Erythematous rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Non blanching rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Vesicular rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Erythema migrans**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Petechial or purpuric rash**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Bruising / ecchymosis**
 | **☐**Yes **☐**No  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **If other type of rash, please specify type and spread:**
 |  | **☐**Centrifugal **☐**Centripetal Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**6) IMAGING** (if available)

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Neuroimaging** | **Results** | **If abnormal, please summarize key results from report:** | **Images attached** | **Report attached** |
| 1. **Cranial ultrasound scan**
 | **☐**Normal **☐**Abnormal **☐**Not Done |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| 1. **MRI brain (record only if part of routine care)**
 | **☐**Normal **☐**Abnormal  |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| 1. **CT brain (record only if part of routine care)**
 | **☐**Normal **☐**Abnormal  |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| 1. **Other (specify type of test):**
 | **☐**Normal **☐**Abnormal  |  | **☐**Yes**☐**No | **☐**Yes**☐**No |
| **Other (specify type of test):** | **☐**Normal **☐**Abnormal  |  | **☐**Yes**☐**No | **☐**Yes**☐**No |

**7) MEDICATIONS OR SUPPORTIVE CARE TO NEONATE POST-DELIVERY**

|  |
| --- |
| 1. **List medications administered within 24 hours of delivery: Use generic names**. Include antibiotics, antivirals, corticosteroids, immunoglobulin, anticonvulsants, diuretics or others.
 |
|  **Type of medication** | **Name of medication**(generic name ) | **Dose** (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: |

**8) LABOUR AND DELIVERY**

|  |  |  |
| --- | --- | --- |
| 1. **Onset of labor**

**☐**Spontaneous **☐**Induced **☐**No labor **☐**Unknown | 1. **Prelabor premature rupture of membranes (PPROM)**

**☐**Yes **☐**No **☐**Unknown | 1. **Place of delivery**

**☐**Home **☐**Health facility **☐**Unknown |
| 1. **Mode of delivery**
 | **☐**Vaginal spontaneous **☐**Vaginal assisted (e.g. forceps , vacuum)**☐**Caesarean section **☐**Assisted breech or breech extraction |
| **If labor was induced, or Caesarean section performed, please tick all that apply:** |
| 1. **Vaginal bleeding**
 | **☐**Yes **☐**No | 1. **Rhesus disease or anti-Kell antibodies**
 | **☐**Yes **☐**No |
| 1. **Placenta previa**
 | **☐**Yes **☐**No | 1. **Intrahepatic cholestasis of pregnancy**
 | **☐**Yes **☐**No |
| 1. **Fetal death**
 | **☐**Yes **☐**No | 1. **Post-term** (>42 weeks’ gestation)
 | **☐**Yes **☐**No |
| 1. **Pregnancy-induced hypertension**
 | **☐**Yes **☐**No | 1. **HIV or AIDS**
 | **☐**Yes **☐**No |
| 1. **Pre-eclampsia**
 | **☐**Yes **☐**No | 1. **Genital tract infection or STD**
 | **☐**Yes **☐**No |
| 1. **Severe pre-eclampsia/eclampsia/ HELLP**
 | **☐**Yes **☐**No | 1. **Infection requiring antibiotics/antivirals**
 | **☐**Yes **☐**No |
| 1. **Breech presentation**
 | **☐**Yes **☐**No | 1. **Accident/maternal trauma**
 | **☐**Yes **☐**No |
| 1. **Fetal distress** (abnormal FHR or BPP)
 | **☐**Yes **☐**No | 1. **Pregnancy termination**
 | **☐**Yes **☐**No |
| 1. **Reduced fetal movement**
 | **☐**Yes **☐**No | 1. **Previous Caesarean section**
 | **☐**Yes **☐**No |
| 1. **Failure to progress**
 | **☐**Yes **☐**No | 1. **Worsening of pre-existing condition** **☐**Yes **☐**No

**If yes** **to above question, specify:** |
| 1. **Cephalo-pelvic disproportion**
 | **☐**Yes **☐**No |
| 1. **PPROM**
 | **☐**Yes **☐**No | 1. **Any other maternal reason** **☐**Yes **☐**No

**If yes to above question, specify**: |
| 1. **Uterine rupture**
 | **☐**Yes **☐**No |
| 1. **Placental abruption**
 | **☐**Yes **☐**No | 1. **Any other fetal reason**  **☐**Yes **☐**No

**If yes to above question, specify**: |
| 1. **Suspected IUGR**
 | **☐**Yes **☐**No |
| 1. If yes to any of the above, specify:
 |
| 1. **Placental weight**
 | \_\_\_\_ | **☐**grams **☐**ounces  |
| 1. **Placental calcifications**
 | **☐**Yes **☐**No **☐**Unknown |
| 1. **Other placental abnormalities**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify:** |  |
| **Intrapartum Complications**  |
| 1. **Hemorrhage**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify source of bleeding:** |  |
| 1. **Chorioamnionitis**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify positive microbiology result:** |  |
| 1. **Fetal hypoxia**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify tests used:** |  |
| 1. **Fetal scalp blood sample**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, record results:** |  |
| 1. **Cardiotocography (CTG) abnormalities**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify:** |  |
| 1. **Other complication(s)**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, specify/describe:** |  |
| **Postpartum Complications** |
| 1. **Postpartum complications (including postpartum hemorrhage)**
 | **☐**Yes **☐**No **☐**Unknown | **If yes, please specify:** |  |
| 1. **Neonatal hypoglycemia**
 | **☐**Yes **☐**No **☐**Unknown | **Please specify glucose value and unit:** (if multiple measurements: note lowest blood glucose value) |  | **☐** mg/dL **☐** mmol/L |

**9) NEONATE HOSPITAL ADMISSION**

|  |  |
| --- | --- |
| 1. **Was the neonate admitted to hospital**
 |  **☐**Yes **☐**No **☐**Unknown |
| 1. **If yes, state the name of the hospital**
 |  |
| 1. **City**
 |  |
| 1. **Reason for admission:**
 |  |
| 1. **Date of admission** (dd/mm/yyyy)
 | \_\_\_ / \_\_\_ / 20\_\_\_\_ | 1. **Length of stay** (days)
 |  \_\_\_\_\_\_ days **☐**Unknown |
| 1. **Was the neonate admitted to intensive care (ITU/PICU/NICU/PHDU)**
 | **☐**Yes **☐**No **☐**Unknown |
|  **If yes, please also complete the Zika virus Case Report Form (CRF) – Neonate Intensive Care module** |

**10) DIAGNOSTIC OUTCOMES NEONATE**

Record the final diagnosis based on laboratory tests performed, clinical picture and case definitions when available. 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. Please complete the Zika virus CRF Neonate Laboratory Results module.

|  |  |  |
| --- | --- | --- |
| **Pathogen** | **Diagnosis** | **Comment** |
| 1. **No confirmed diagnosis**
 | **☐** Tick if no diagnosis made |  |
| 1. **Zika virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Dengue virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Yellow fever virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **West Nile virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Chikungunya virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Toxoplasmosis**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Rubella**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Cytomegalovirus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **Herpes Simplex virus**
 | **☐** Confirmed acute infection**☐**Probable acute infection**☐**Confirmed past infection**☐**Probable past infection**☐**Negative **☐**Not tested **☐**Unknown |  |
| 1. **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  |  |

**11) NEONATE OUTCOME AT DISCHARGE**

Complete at discharge or death

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Date of discharge** (dd/mm/yyyy): \_\_ / \_\_ / 20 \_\_\_\_
2. **Neonate’s status at discharge:**

**☐** Discharged home or other place with no abnormalities **☐** Discharged home or other place with neurological sequelae (e.g. seizures, spasticity, hypotonia, abnormal movements) **☐** Discharged home or other place with birth abnormality **☐** Antepartum death **☐** Intrapartum death**☐** Unknown1. **Microcephaly (as defined in the study inclusion criteria):** **☐**Yes **☐**No **☐**Unknown
2. **If discharged with neurological sequelae, please specify:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**1. **If discharged with other abnormality specify all:**

|  |  |  |
| --- | --- | --- |
| Infant abnormality |  |  |
| Microcephaly | **☐**Present **☐**Absent  |  |
| Facial disproportion | **☐**Present **☐**Absent |  |
| Hearing impairments | **☐**Present **☐**Absent |  |
| Visual impairments | **☐**Present **☐**Absent |  |
| Dysphagia | **☐**Present **☐**Absent |  |
| Calcifications - CNS imaging | **☐**Present **☐**Absent |  |
| Epilepsy and seizures | **☐**Present **☐**Absent |  |
| Spasticity/contractures | **☐**Present **☐**Absent |  |
| Neurological reflexes | **☐**Present **☐**Absent |  |
| Cerebral palsy | **☐**Present **☐**Absent |  |
| Other, specify: |  |

**DIAGNOSTICS OUTCOME**1. **Zika virus ☐**Positive **☐**Probable **☐**Negative **☐**Unknown **☐**Not tested
2. **Diagnosis confirmed by: ○** Lab. confirmed locally **○** Lab. confirmed by regional reference laboratory

 **○** Other, specify :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 1. **Case definition/certainty of diagnosis (in line with national definitions):**

**☐**Possible **☐**Probable **☐**Confirmed **Comment on case definition:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **If deceased please specify date of death** (dd/mm/yyyy)**:** \_\_ / \_\_ / 20 \_\_\_
2. **Was autopsy performed: ☐**Yes  **☐**No **☐**Unknown **Date of autopsy:** \_\_ / \_\_ / 20 \_\_\_
3. **Any other outcome, describe all:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**12) CASE REPORT FORM COMPLETED BY**

|  |  |
| --- | --- |
| **Name and role** |  |
| **Signature** |  | **Date** (dd/mm/yyyy) | \_\_\_\_ / \_\_\_\_ / 20 \_\_\_\_ |

1. http://www.himfg.edu.mx/descargas/documentos/EDI/ManualdeExploracionNeurologicaparaNinosMenoresde5enelPrimerySegundoNiveldeAtencion.pdf [↑](#footnote-ref-1)