ZIKA VIRUS CASE REPORT FORMS – NEONATE BASELINE AND OUTCOME – (NBO)

Neonate's Identification Code : _____ Mother'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.

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.

ZIKA VIRUS CASE REPORT FORMS – NEONATE BASELINE AND OUTCOME – (NBO)

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- 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		
2. Geoposition	**Latitude:**___ . _____	**Longitude:** ___ . _____
If geoposition not available, state location below		
3. City/town/village:		
4. Country (& region/district):		

1) NEONATE DEMOGRAPHICS

5. Sex	☐Male ☐Female ☐Uncertain
6. Date of birth (dd/mm/yyyy)	____ / ____ / 20 ____
7. Gestational age at birth	____ weeks ____ days
8. Basis of gestational age estimation at birth	☐Last menstrual period ☐Ultrasound ☐Assisted reproduction ☐Other (specify):
9. Birth number	☐Singleton ☐Twin I ☐Twin II ☐Triplet I ☐Triplet II ☐Triplet III ☐Other: _____
10. Ethnicity of baby (as per national guidelines):	
11. Fetal presentation at delivery	☐Cephalic ☐Breech ☐Other (specify):

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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.**

12. Apgar scores ☐ Yes ☐ Not done If yes give scores	____ 1min ____ 5min ____ 10min					
13. Birth weight (<12 hrs after delivery) ☐ Yes ☐ Not done If yes give measurements	____	grams	____	pounds	____	ounces
14. Crown-to-heel length ☐ Yes ☐ Not done If yes give measurements	____	cm	____	inches		
15. 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	**16. Birth weight** ____SD		**17. Crown-to-heel length** ____ SD		**18. Head circumference** ____ SD	
19. Mother's head circumference ☐ Yes ☐ Not done If yes give measurements	____	cm	____	inches		
20. 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

21. Fontanelle present	**Anterior:** ☐Yes ☐No ☐Unknown	**Posterior:** ☐Yes ☐No ☐Unknown	**Bulging:** ☐Yes ☐No ☐Unknown
22. Abnormal skull shape	☐Yes ☐No ☐Unknown	☐ Oxicefalia ☐ Plagiocefalia ☐ Trigocefalia ☐ Escafocefalia ☐ Acrocefalia	

Neonate's Identification Code : _____ Mother's Identification Code : _____

If yes, circle most appropriate depiction[1]:

Oxicefalia

Plagiocefalia

Trigocefalia

Escafocefalia

Acrocefalia

23. Sloping forehead	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
24. Craniosynostosis	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
25. Cephalohematoma	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
26. Subgaleal hemorrhage	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
27. Redundant skin on skull at birth	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
28. Facial disproportion	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**
29. Nasal abnormalities	☐Yes ☐No ☐Unknown	
30. Flat nasal bridge	☐Yes ☐No ☐Unknown	
31. Anteverted nares	☐Yes ☐No ☐Unknown	
32. Other nasal abnormalities	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**

[1]http://www.himfg.edu.mx/descargas/documentos/EDI/ManualdeExploracionNeurologicaparaNinosMenoresde5enelPrimerySegundoNiveldeAtencion.pdf

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

33. Orofacial clefts	☐Yes ☐No ☐Unknown ☐ Cleft lip ☐ Cleft palate ☐ Both	☐left ☐right ☐middle ☐bilateral
34. Eye abnormalities	☐Yes ☐No ☐Unknown ☐Anophthalmia ☐Microphthalmia	☐ **Other (describe):**
35. Ear abnormalities	☐Yes ☐No ☐Unknown ☐ Anotia (absent ear/s) ☐ Microtia (small ear/s)	☐ **Other (describe):**
36. Hemangiomas	☐ Present ☐ Absent	o Facial o Rest of body Number of them:_____
37. Neural tube defects	☐Yes ☐No ☐Unknown ☐ Spina bifida ☐ Meningocele ☐ Anencephaly	☐ **Other (describe):**
38. Scoliosis **39. Barrel-like chest**	☐Yes ☐No ☐Unknown ☐Yes ☐No ☐Unknown	
40. Upper Limb abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown Arthrogryposis ☐Yes ☐No Amyoplasia ☐Yes ☐No If yes: ☐Distal ☐Syndromic Hyperextension ☐Yes ☐No If yes, indicate joints: _____ _____ Contractures ☐Yes ☐No If yes, indicate joints: _____ _____	☐**Other (describe):**
41. Hand abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown o Clinodactyly ☐ Unilateral ☐ Bilateral o Missing digits ☐ Unilateral ☐ Bilateral o Extra digits ☐ Unilateral ☐ Bilateral o Camptodactyly ☐ Unilateral ☐ Bilateral o Nail hypoplasia/aplasia o Adducted thumb o Bilateral simian crease	☐**Other (describe):**

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

42. Lower Limb abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown Arthrogryposis ☐Yes ☐No Amyoplasia ☐Yes ☐No If yes: ☐Distal ☐Syndromic Hyperextension ☐Yes ☐No If yes, indicate joints): _____ _____ Joint dislocation/subluxation ☐Yes ☐No If yes, indicate joints): _____ _____ Contractures ☐Yes ☐No If yes, indicate joints): _____ _____	☐**Other (describe):**
43. Feet abnormalities **If yes, specify/describe:**	☐Yes ☐No ☐Unknown o Widely spaced toes ☐ Unilateral ☐Bilateral o Missing toes ☐ Unilateral ☐Bilateral o Extra toes ☐ Unilateral ☐Bilateral o Clubfoot ☐ Unilateral ☐Bilateral o Nail ☐ Unilateral ☐Bilateral	☐**Other (describe):**
44. Umbilical hernia	☐ Present ☐ Absent	
45. Gastroschisis	☐Yes ☐No ☐Unknown	
46. Omphalocele	☐Yes ☐No ☐Unknown	
47. 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):**
48. Down's syndrome features	☐Yes ☐No ☐Unknown	
49. Known familial genetic disorders	☐Yes ☐No ☐Unknown	**If yes, please specify:**

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

50. 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:**	
51. Fundoscopy	☐Normal ☐Abnormal ☐Not Done		
52. Red reflex	☐Present ☐Absent ☐Not Done		
53. Cataract	☐Normal ☐Abnormal ☐Not Done		
54. Chorioretinitis	☐ Absent ☐ Present ☐ Examination Not Done		
55. Hearing test	☐Normal ☐Abnormal ☐Not Done	**Specify test used:**	
56. Congenital heart defects	☐Yes ☐No ☐Unknown	**If yes, specify:**	
57. Any other significant findings	☐Yes ☐No	**If yes, specify:**	
Newborn blood screening	**58. Hypothyroidism** ☐Negative ☐Positive ☐Not Done	**59. Phenylketonuria** ☐Negative ☐Positive ☐Not Done	**60. 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.*

61. Date (dd/mm/yyyy)	__ __ / __ __ / 20 __ __	
General physical examination		
62. Maximum temperature	____.__°C or _____ Fahrenheit ☐Oral ☐Tympanic ☐Axillary ☐Anal ☐Skin ☐Other (specify):	
63. Respiratory rate		breaths/minute ☐ Not done
64. Heart rate		beats/minute ☐ Not done
65. Capillary refill time (central)		Seconds ☐ Not done
66. Peripheral O_2 saturation (SpO_2)		% ☐ Not done

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

67. Cardiovascular system	☐Normal ☐Abnormal ☐Unknown	☐Murmur ☐Other (specify) :	
68. Respiratory system	☐Normal ☐Abnormal ☐Unknown	If abnormal, describe:	
69. Gastrointestinal system	☐Normal ☐Abnormal ☐Unknown	☐Jaundice ☐Abdominal tenderness ☐Hepatomegaly ☐Splenomegaly ☐Other (specify):	
70. Edema	☐Yes ☐No ☐Unknown	**If yes, describe affected parts:**	
71. Cryptorchidism	☐Yes ☐No ☐Unknown ☐ Not applicable		
72. Type of cry	☐Strong normal cry ☐Weak, high-pitched or continuous cry ☐Not crying ☐Other:		
Neurological examination			
73. Tonic neck reflex	☐ Symmetrical ☐ Asymmetrical ☐Absent ☐Not Done		
74. Sucking reflex	☐ Present ☐ Absent		
75. Grasp reflex	**Left foot** ☐ Present ☐ Absent	**Right foot** ☐ Present ☐ Absent	
	Left hand ☐ Present ☐ Absent	**Right hand** ☐ Present ☐ Absent	
76. Moro reflex	☐Present ☐Absent ☐Not Done	☐Symmetrical ☐Asymmetrical	
77. Rooting reflex	☐Present ☐Absent ☐Not Done		
78. 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

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

	Achilles tendon	☐Present ☐Absent ☐Not Done	☐Present ☐Absent ☐Not Done
79. Muscle tone	☐Normal ☐Hypertonic ☐Hypotonic	If hypertonic, specify which limbs involved:	
80. Extremity movements	☐Symmetrical ☐Asymmetrical ☐Unknown		
81. 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):		
82. Paralysis	☐General ☐Ascending ☐No ☐Unknown	**If yes, describe:**	
83. Contractures	☐Yes ☐No ☐Unknown	**If yes, describe:**	
84. Other neurological signs*	☐Yes ☐No	**If yes, describe:**	
85. Other abnormal movements* e.g. writhing movements	☐Yes ☐No	**If yes, describe:**	
Skin abnormalities			
86. Rash	☐Yes ☐No ☐Unknown	**If yes, date of rash onset** (dd/mm/yyyy)	__ __ / __ __ / 20 __ __
If yes, describe type of rash		**Body distribution of rash**	
87. Maculopapular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____	
88. Erythematous rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____	
89. Non blanching rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____	
90. Vesicular rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____	
91. Erythema migrans	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____	

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

92. Petechial or purpuric rash	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
93. Bruising / ecchymosis	☐Yes ☐No	☐Centrifugal ☐Centripetal Location:_____
94. 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**
95. Cranial ultrasound scan	☐Normal ☐Abnormal ☐Not Done		☐Yes ☐No	☐Yes ☐No
96. MRI brain (record only if part of routine care)	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
97. CT brain (record only if part of routine care)	☐Normal ☐Abnormal		☐Yes ☐No	☐Yes ☐No
98. 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

99. 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:

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

						☐IV ☐Oral ☐Rectal ☐Other:
						☐IV ☐Oral ☐Rectal ☐Other:
						☐IV ☐Oral ☐Rectal ☐Other:

8) LABOUR AND DELIVERY

100. Onset of labor ☐Spontaneous ☐Induced ☐No labor ☐Unknown	**101. Prelabor premature rupture of membranes (PPROM)** ☐Yes ☐No ☐Unknown	**102. Place of delivery** ☐Home ☐Health facility ☐Unknown

103. 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:

104. Vaginal bleeding	☐Yes ☐No	**105. Rhesus disease or anti-Kell antibodies**	☐Yes ☐No
106. Placenta previa	☐Yes ☐No	**107. Intrahepatic cholestasis of pregnancy**	☐Yes ☐No
108. Fetal death	☐Yes ☐No	**109. Post-term** (>42 weeks' gestation)	☐Yes ☐No
110. Pregnancy-induced hypertension	☐Yes ☐No	**111. HIV or AIDS**	☐Yes ☐No
112. Pre-eclampsia	☐Yes ☐No	**113. Genital tract infection or STD**	☐Yes ☐No
114. Severe pre-eclampsia/eclampsia/ HELLP	☐Yes ☐No	**115. Infection requiring antibiotics/antivirals**	☐Yes ☐No
116. Breech presentation	☐Yes ☐No	**117. Accident/maternal trauma**	☐Yes ☐No
118. Fetal distress (abnormal FHR or BPP)	☐Yes ☐No	**119. Pregnancy termination**	☐Yes ☐No
120. Reduced fetal movement	☐Yes ☐No	**121. Previous Caesarean section**	☐Yes ☐No
122. Failure to progress	☐Yes ☐No	**123. Worsening of pre-existing condition** ☐Yes ☐No **If yes to above question, specify:**	
124. Cephalo-pelvic disproportion	☐Yes ☐No		
125. PPROM	☐Yes ☐No	**126. Any other maternal reason** ☐Yes ☐No **If yes to above question, specify**:	
127. Uterine rupture	☐Yes ☐No		
128. Placental abruption	☐Yes ☐No	**129. Any other fetal reason** ☐Yes ☐No **If yes to above question, specify**:	
130. Suspected IUGR	☐Yes ☐No		

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

131. If yes to any of the above, specify:			
132. Placental weight	____	☐grams ☐ounces	
133. Placental calcifications	☐Yes ☐No ☐Unknown		
134. Other placental abnormalities	☐Yes ☐No ☐Unknown	**If yes, specify:**	
Intrapartum Complications			
135. Hemorrhage	☐Yes ☐No ☐Unknown	**If yes, specify source of bleeding:**	
136. Chorioamnionitis	☐Yes ☐No ☐Unknown	**If yes, specify positive microbiology result:**	
137. Fetal hypoxia	☐Yes ☐No ☐Unknown	**If yes, specify tests used:**	
138. Fetal scalp blood sample	☐Yes ☐No ☐Unknown	**If yes, record results:**	
139. Cardiotocography (CTG) abnormalities	☐Yes ☐No ☐Unknown	**If yes, specify:**	
140. Other complication(s)	☐Yes ☐No ☐Unknown	**If yes, specify/describe:**	
Postpartum Complications			
141. Postpartum complications (including postpartum hemorrhage)	☐Yes ☐No ☐Unknown	**If yes, please specify:**	
142. 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

143. Was the neonate admitted to hospital	☐Yes ☐No ☐Unknown
144. If yes, state the name of the hospital	
145. City	
146. Reason for admission:	

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

147. Date of admission (dd/mm/yyyy)	___ / ___ / 20____	**148. Length of stay** (days)	_____ days ☐Unknown
149. 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
150. No confirmed diagnosis	☐ Tick if no diagnosis made	
151. Zika virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
152. Dengue virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
153. Yellow fever virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
154. West Nile virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

155. Chikungunya virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
156. Toxoplasmosis	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
157. Rubella	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
158. Cytomegalovirus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
159. Herpes Simplex virus	☐ Confirmed acute infection ☐Probable acute infection ☐Confirmed past infection ☐Probable past infection ☐Negative ☐Not tested ☐Unknown	
160. 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	

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

11) NEONATE OUTCOME AT DISCHARGE

Complete at discharge or death

161. Date of discharge (dd/mm/yyyy): __ / __ / 20 ____

162. 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
☐ Unknown

163. Microcephaly (as defined in the study inclusion criteria): ☐Yes ☐No ☐Unknown

164. If discharged with neurological sequelae, please specify:

_____

_____

_____

165. 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

166. Zika virus ☐Positive ☐Probable ☐Negative ☐Unknown ☐Not tested

167. Diagnosis confirmed by: ○ Lab. confirmed locally ○ Lab. confirmed by regional reference laboratory
○ Other, specify :_____

168. Case definition/certainty of diagnosis (in line with national definitions):

☐Possible ☐Probable ☐Confirmed

Comment on case definition:_____

169. If deceased please specify date of death (dd/mm/yyyy): __ / __ / 20 ___

170. Was autopsy performed: ☐Yes ☐No ☐Unknown **Date of autopsy:** __ / __ / 20 ___

171. Any other outcome, describe all:_____

Neonate's Identification Code : _____ **Mother's Identification Code :** _____

_____

_____

12) CASE REPORT FORM COMPLETED BY

Name and role			
Signature		**Date** (dd/mm/yyyy)	____ / ____ / 20 ____