



**CRF Completion Guidelines (CCGs)**  
**Protocol #: MTN-042B**  
V3.0 (10 October 2019)

## Completion Guidelines for MTN-042B REDCap CRF

The following instructions are study-specific data completion instructions intended to assist site staff when completing the REDCap Case Report Form (CRF) for MTN-042B.

### Item-specific Instructions:

Field	Instructions
1. Study Assigned Maternal Patient ID (PTID)	Enter the 5-digit numeric PTID assigned using the facility-specific PTID linkage log.
<b>Delivery Data</b>	
2. Number of infants resulting from this delivery	Select the number of infants (Including stillbirths) resulting from this delivery. If a pregnancy results in more than 3 infants, please contact Management Team.
3. Date of Delivery	Enter the date of delivery using the “dd-mm-yyyy” format, where “dd” represents the two-digit day, “mm” represents the two-digit month, and “yyyy” represents the four digits of the year.
4. Maternal age	Using <u>numbers only</u> , enter maternal age.  If maternal age is unknown, leave blank and check the <i>4a. Age not documented</i> checkbox. A response is required for either 4. or 4a.
5. Gravity	Using <u>numbers only</u> , enter the number of times the patient has been pregnant (including this pregnancy).  If gravity is unknown, leave blank and check the <i>5a. Gravity not documented</i> checkbox. A response is required for either 5. or 5a.
6. Parity	Using <u>numbers only</u> , enter the number of times the patient has carried a pregnancy to a viable gestational age (as reported in the patient medical record).  Note: Miscarriages should not be explicitly described in this field; miscarriages can be calculated from gravity and parity.  If parity is unknown, leave blank and check the <i>6a. Parity not documented</i> checkbox. A response is required for either 6. or 6a.
7. Did this patient attend antenatal care?	If site staff were able to ascertain if the patient attended antenatal care, select “yes” or “no”. If unknown, select “not documented”.  If “yes”, complete 7a.
7a. If yes, number of ANC visits attended	If site staff were able to ascertain the number of antenatal care visits attended, select the number. If unknown, select “Not documented”.
8. Maternal HIV Status	Select maternal HIV status. If the patient chart does not document HIV status, or does not state that HIV status is unknown, select “Not documented”.

Field	Instructions
9. Was the patient transferred to this hospital for delivery from a different facility?	Select "yes" or "no".
10. Was the patient transferred from this hospital to a different facility after delivery?	Select "yes" or "no".
11. Was maternal death documented in chart	Select "yes" or "no".
<b>Pregnancy Complications</b>	
12. Hypertension	Select "yes" if hypertension is documented in the patient chart or is presumed based on chart review.  If "yes", complete 12a and 12b.
12a. Hypertension, specify	Select the most severe diagnosis.  "Gestational" should be selected if Pregnancy >20 weeks and NEW diagnosis of hypertension ( $\geq 140$ mmHg systolic and/or $\geq 90$ mmHg) WITHOUT severe features of pre-eclampsia or proteinuria.  "Pre-eclampsia WITHOUT severe features" should be selected if pregnancy >20 weeks and NEW diagnosis of hypertension ( $\geq 140$ mmHg systolic and/or $\geq 90$ mmHg) AND proteinuria BUT no severe features which include <ul style="list-style-type: none"> <li>• Severely elevated blood pressures, with systolic blood pressure <math>\geq 160</math> mmHg and/or diastolic blood pressure <math>\geq 110</math> mmHg, which is confirmed after only minutes (to facilitate timely antihypertensive treatment)</li> <li>• Development of a severe headache (which can be diffuse, frontal, temporal or occipital) that generally does not improve with over the counter pain medications (such as acetaminophen/paracetamol)</li> <li>• Development of visual changes (including photopsia, scotomata, cortical blindness)</li> <li>• Eclampsia, or new-onset grand mal seizures in a patient with preeclampsia, without other provoking factors (such as evidence of cerebral malaria or preexisting seizure disorder). Seizures are often preceded by headaches, visual changes or altered mental status</li> <li>• New onset thrombocytopenia, with platelet count <math>&lt; 100,000/\mu\text{L}</math></li> <li>• New onset of nausea, vomiting, epigastric pain</li> <li>• Transaminitis (AST and ALT elevated to twice the upper limit of normal)</li> <li>• Liver capsular hemorrhage or liver rupture</li> <li>• Worsening renal function, as evidenced by serum creatinine level greater than 1.1 mg/dL or a doubling of the serum creatinine (absent other renal disease)</li> <li>• Oliguria (urine output <math>&lt; 500</math> mL/24 h)</li> <li>• Pulmonary edema (confirmed on clinical exam or imaging)</li> </ul>

Field	Instructions
12b. Hypertension diagnosis	Indicate whether diagnosis term is recorded in patient chart or if the diagnosis term is presumed based on chart review.  If "Diagnosis term not recorded in chart but presumed based on chart review", complete 12c.
12c. Hypertension diagnosis presumed rationale	Specify rationale for using term not recorded in chart. Try to use 1-2 sentences to justify why you selected this diagnosis.
13. Post partum hemorrhage	Select "yes" if post-partum hemorrhage is documented in the patient chart or is presumed based on chart review.  If "yes", complete 13a.
13a. Post partum hemorrhage diagnosis	Indicate whether diagnosis term is recorded in patient chart or if the diagnosis term is presumed based on chart review.  If "Diagnosis term not recorded in chart but presumed based on chart review", complete 13b.
13b. Post partum hemorrhage: Rationale for using term not recorded in chart	Specify rationale for using term not recorded in chart. Try to use 1-2 sentences to justify why you selected this diagnosis.
14. Fever of unclear etiology	Select "yes" if fever of unclear etiology is documented in the patient chart or is presumed based on chart review.  If "yes", complete 14a.
14a. Fever of unclear etiology diagnosis	Indicate whether diagnosis term is recorded in patient chart or if the diagnosis term is presumed based on chart review.  If "Diagnosis term not recorded in chart but presumed based on chart review", complete 14b.
14b. Fever of unclear etiology: Rationale for using term not recorded in chart	Specify rationale for using term not recorded in chart. Try to use 1-2 sentences to justify why you selected this diagnosis.
15. Chorioamnionitis	Select "yes" if chorioamnionitis is documented in the patient chart or is presumed based on chart review. Presumed chorioamnionitis may include mother with temp >38 degrees Celsius and treated with antibiotics during labor.  If "yes", complete 15a.
15a. Chorioamnionitis diagnosis	Indicate whether diagnosis term is recorded in patient chart or if the diagnosis term is presumed based on chart review.  If "Diagnosis term not recorded in chart but presumed based on chart review", complete 15b.

Field	Instructions
15b. Chorioamnionitis: Rationale for using term not recorded in chart	Specify rationale for using term not recorded in chart. Try to use 1-2 sentences to justify why you selected this diagnosis.
16. Post partum endometritis	Select "yes" if post-partum endometritis of unclear etiology is documented in the patient chart or is presumed based on chart review. Presumed post partum endometritis may include mother with temp >38 degrees Celsius after delivery and treated with antibiotics  If "yes", complete 16a.
16a. Post partum endometritis diagnosis	Indicate whether diagnosis term is recorded in patient chart or if the diagnosis term is presumed based on chart review.  If "Diagnosis term not recorded in chart but presumed based on chart review", complete 16b.
16b. Post partum endometritis: Rationale for using term not recorded in chart	Specify rationale for using term not recorded in chart. Try to use 1-2 sentences to justify why you selected this diagnosis.
<p>Infant sections: Depending on the response to 2. <i>Number of infants resulting from this delivery</i>, the following sections will be visible:</p> <ul style="list-style-type: none"> <li>- Infant #1 and Infant #1 Data</li> <li>- Infant #2 and Infant #2 Data</li> <li>- Infant #3 and Infant #3 Data</li> </ul> <p>Each section will include questions 17 – 23 below.</p>	
17. Place of infant delivery	Enter the place of delivery/outcome. If the delivery occurred in transit, select "at home". If data is not available in the patient chart, select "not documented".
18. Pregnancy primary outcome	Specify the pregnancy outcome. If data is not available in the medical chart, select "not documented".  If "full term live birth ( $\geq 37$ weeks)" or "premature live birth (< 37 weeks)", complete questions 19 – 23.  If "not documented", complete questions 19 – 23, if data is available.  If "still born/intrauterine fetal demise", complete questions 18a. <i>Still born/intrauterine fetal demise, specify</i> and 23.
18a. Still born/intrauterine fetal demise, specify	Specify whether still born/intrauterine fetal demise was macerated, fresh, or unknown. A "macerated" fetus shows skin and soft-tissue changes suggesting death was well before delivery. A "fresh" fetus lacks such skin changes and is presumed to have died much more recently.

Field	Instructions
19. Mode of delivery	<p>If “Vaginal delivery”, complete <i>19a. Vaginal delivery type</i>.</p> <p>If a delivery is vaginal, but breech, select “Other” and enter “Vaginal breech” in <i>19b. Mode of delivery other specify</i>.</p> <p>If “Other”, complete <i>19b. Mode of delivery, other specify</i>.</p>
20. Birthweight recorded	Select “yes” if birthweight is recorded in patient chart. If “yes”, complete <i>20a. Birthweight in grams</i> .
21. Neonatal death (infant died AFTER delivery within 7 days of life)	Select “yes” or “no”.
22. Neonatal ICU admission within 7 days of life or transferred to a higher care facility	Select “yes” or “no”.
23. Congenital Malformations identified at delivery	Record if any fetal/infant congenital anomalies were identified. If “yes”, select all applicable items for <i>23a</i> .
23a. Congenital Malformations identified at delivery type	<p>If there were fetal/infant congenital malformations identified, then check all that apply.</p> <p>If “Other” is selected, complete <i>23b. Congenital malformation: other, specify</i></p>
Form Status	
Complete?	<p>The “Form Status” item in REDCap is used to track the status of each record.</p> <p>Select “Incomplete” if data collection is not complete and a data abstractor needs to review the chart again at a later date.</p> <p>Select “Unverified” if data collection is complete and the chart has been selected for QC step #2.</p> <p>Select “Complete” if data collection is complete and the chart has NOT been selected for QC step #2.</p>