

CRF – Infant Outcome		
No	Question	Response
001a	Outcome:	0 = Non-living 1 = Living
001b	Is the infant enrolled in the study?	0 = No   skip to 001d 1 = Yes
001c	Date of enrollment (i.e., DOB):	— — / — — / — — — — D D / M M / Y Y Y Y
001d	Why did infant not enroll in the study?	<b>Respond only if [001b = 0]</b>  0 = Fetal demise/stillbirth/non-viable pregnancy 1 = Infant consent was withdrawn 2 = Other
001e	Please specify why infant was not enrolled in the study:	<b>Respond only if [001d = 0]</b>
<p>If Ultrasound results allowed identification of multiple fetuses, each was assigned an ID of A, B, C, D, etc. This ID allows linkage between pre-natal records and post-natal records for infants regardless of enrollment status.</p>		
002	Fetus ID assigned from ultrasound results:	
004	GA on date of outcome	
005	Type of outcome:	<b>Dependent on 001a and 003</b>  0 = Full term live birth (≥37 weeks) 1 = Premature live birth (<37 weeks) 2 = Pregnancy loss at or after 20 weeks 3 = Pregnancy loss before 20 weeks

006	Is there a medical record that <b>provides a different outcome</b> from the above calculated outcome?	0 = No 1 = Yes
007	How does the medical record categorize this outcome?	<b>Respond only if [006 = 1]</b>  0 = Full term live birth (≥37 weeks) 1 = Premature live birth (<37 weeks) 2 = Pregnancy loss at or after 20 weeks 3 = Pregnancy loss before 20 weeks
008	Explain the discrepancy, including what data was provided on the record	<b>Respond only if [006 = 1]</b>
009	Delivery method:	0 = No delivery/pregnancy loss 1 = Vaginal delivery - normal, unassisted 2 = Vaginal delivery - normal, assisted (forceps, vacuum) 3 = Cesarean delivery (emergency) 4 = Cesarean delivery (elective) 5 = Cesarean delivery (unable to determine type)
010	If vaginal, was it a breech delivery for this particular infant?	<b>Respond only if [009 = 1 or 2]</b>  0 = No 1 = Yes
011	Type of fetal demise/stillbirth:	<b>Respond only if [001a = 0]</b>  0 = Macerated (antenatal) 1 = Fresh (intrapartum, i.e., fetal heart rate presence or rate recorded in intrapartum record)
012	Was this a spontaneous preterm delivery?	<b>Respond only if [005 = 1]</b>  0 = No 1 = Yes
013	What was the reason for delivery?	<b>Respond only if [005 = 1]</b>
014	Fetal/infant sex	0 = Male 1 = Female 2 = Intersex
015	Were any fetal/infant congenital anomalies identified prior to this visit?	<b>Select all that apply</b>  <b>If [2-13] then document on the Medical Event/Conditions CRF (under infant's record for</b>

		<p>enrolled infants, under maternal record for non-enrolled fetuses)</p> <p>0 = None  1 = Not obtainable  2 = Cleft lip and/or palate  3 = Neural tube defects  4 = Hydrocephalus  5 = Cardiovascular  6 = Polydactyly  7 = Musculoskeletal including clubfoot  8 = Umbilical hernia  9 = Esophageal, gastrointestinal, anorectal  10 = Genitourinary  11 = Trisomies  12 = Natal tooth  13 = Other</p>
016	Specify the 'other' congenital anomalies that were identified:	Respond only if [015 = 13]
017	Did the infant receive any resuscitation efforts at birth?	0 = No   Skip to 019 1 = Yes
018	Please describe the resuscitation efforts:	
019	Did infant require any additional special care after delivery (for example antibiotics, NICU stay, respiratory support)?	0 = No   Skip 10 1 = Yes
020	Please describe the special care that the infant received after delivery:	

**Infant metrics at or around time of delivery**

Section is populated only if [004 is not 3 ]

021	Infant birth weight (g):	If <2500 g, document on enrolled infant <b>Medical Event/Conditions CRF</b>
022	Infant birth length (cm):	
023	Infant head circumference (cm):	
024	Infant body temperature (C):	
025	Route of temperature:	0 = Axillary 1 = Rectal
026	Infant pulse (beats/min):	
027	Infant rate of respiration (breaths/min):	
028	Apgar score 1 minute	
029	Apgar score 5 minutes	
030	Does the infant have any medical events/conditions to report since birth?	0 = No 1 = Yes   Document on enrolled infant <b>Medical Event/Conditions CRF</b>
031	Has the infant participant been given any medications since birth?	0 = No 1 = Yes   Document on enrolled infant <b>Medications CRF</b>
032	Has the infant had any other contact with the health system since birth, e.g., hospitalization, specialist care, diagnostic testing, etc.?	0 = No 1 = Yes   Document on <b>Healthcare Provider Form</b> 2 = Plans to obtain care   Document on <b>Healthcare Provider Form</b>

033	Where any medical records reviewed?  <b>Note: document record type in chart notes</b>	<b>Select all that apply</b>  0 = No 1 = Yes, handheld along with participant report 2 = Yes, abstracted from medical records
034	CRF Notes	