Form: EVW10009: Delivery Record (Infant Enrolled)

Form version: 1.000

INSTRUCTIONS:

• Use the 24-hour clock where 00:00 is midnight.

• In the case of multiple births, add a new log line for each infant.

1. - Is information available about delivery?
   - ☐ Yes
   - ☐ No

2. - Infant PID Number: _____

3. - Infant's date of birth: _____

4. - Infant's time of birth: _____

5. - Infant's biological sex at birth:
   - ☐ Male
   - ☐ Female
   - ☐ Ambiguous genitalia/Intersex
   - ☐ Unknown

6. - Obstetrical estimate of gestational age:
   a. Weeks [nn]: _____

   b. - Days [n]: _____

7. - Presentation:
   - ☐ Vertex
   - ☐ Breech
   - ☐ Transverse

8. - Did the membranes rupture?
   - ☐ Yes
   - ☐ No
   - ☐ Unknown

   a. - How did the membranes rupture?
      - ☐ Spontaneous
      - ☐ Amniotomy
      - ☐ Unknown

   b. - Is the date the membranes ruptured available?
      - ☐ Yes
      - ☐ No

      Indicate date: _____

   c. - Is the time the membranes ruptured available?
      - ☐ Yes
      - ☐ No

      Indicate time: _____

   d. - How long prior to delivery did the membranes rupture?
      - ☐ 0-<4 hours
      - ☐ 4-<6 hours
      - ☐ 6-<12 hours
      - ☐ 12-24 hours
      - ☐ >24 hours
      - ☐ Unknown

9. - Delivery location:
   - ☐ Home
   - ☐ Hospital

	Clinic ☐
	En route ☐
	Other ☐
a. - If Other, specify [70]:	_____
b. - Is the date of hospital or clinic admission available?	Yes ☐
	No ☐
Date of admission:	_____
c. - Is the time of hospital or clinic admission available?	Yes ☐
	No ☐
Time of admission:	_____
d. - Name of hospital/clinic [70]:	_____
10. - Type of delivery:	Assisted vaginal ☐
	Unassisted vaginal ☐
	Unknown vaginal ☐
	Elective cesarean ☐
	Emergency cesarean ☐
	Unknown cesarean ☐
a. - What was the primary indication for the Cesarean section?	Arrest disorder ☐
	Non-reassuring fetal heart rate (FHR) ☐
	Malpresentation ☐
	Previous cesarean ☐
	Placenta previa ☐
	Placenta abruptio ☐
	Cephalo-pelvic disproportion (CPD) ☐
	Active or recent vaginal infection/inflammation including STI's ☐
	Failed induction ☐
	Prolonged rupture of membranes (PROM) ☐
	Pre-eclampsia ☐
	Eclampsia ☐
	Cord prolapse ☐
	Failure to descend ☐
	Multiple gestation ☐
	Fetal anomaly ☐
	Macrosomia ☐
	Protraction and/or arrest of labor ☐
	Fetal distress ☐
	Reduction of MTCT risk (e.g. detectable maternal HIV RNA) ☐
	Genital herpes simplex virus (HSV) ☐
	Subject request/desire ☐
	Other maternal indication ☐

Other infant indication ☐

If Other, specify [70]: _____

11. - Was the Amniotic Fluid examined? Yes ☐ No ☐

a. Examination of amniotic fluid:

Normal: ☐

Meconium: ☐

Blood: ☐

Fetid/foul odor: ☐

Form version: 1.000

This is a maternal form collecting data on labor prior to delivery.

INSTRUCTIONS:

Use the 24-hour clock where 00:00 is midnight.

1. - Number of fetuses/infants:
- 1 ☐
- 2 ☐
- 3 ☐

2. - Was the mother in labor prior to delivery?
- Yes ☐
- No ☐
- Unknown ☐

a. - Is the date labor began available?
- Yes ☐
- No ☐

Enter the date labor began: _____

b. - Is the time labor began available?
- Yes ☐
- No ☐

Enter the time labor began: _____

c. - How long prior to delivery did labor begin?
- 0-<4 hours ☐
- 4-<6 hours ☐
- 6-<12 hours ☐
- 12-24 hours ☐
- >24 hours ☐
- Unknown ☐

d. - Was labor spontaneous or induced?
- Spontaneous ☐
- Induced ☐

If Induced, what is the indication for induction?
- Gestational hypertension (e.g., preeclampsia, eclampsia, HELLP) ☐
- Worsening maternal chronic hypertension ☐
- Other maternal chronic disease (e.g. diabetes mellitus, renal disease, chronic pulmonary disease) ☐
- Chorioamnionitis ☐
- Post-term pregnancy ☐
- Fetal growth restriction ☐
- Oligohydramnios ☐
- Isoimmunization ☐
- Abnormal fetal testing ☐
- Twin gestation ☐

	Placental abruption ☐
	Cholestasis of pregnancy ☐
	Fetal death ☐
	Prolonged rupture of membranes (PROM) ☐
	Other maternal reason ☐
	Other fetal reason ☐
If Other, specify [70]:	
3. - Were any of the following procedures performed on the mother during labor?	Yes ☐
	No ☐
If Yes, check all that apply:	Unknown ☐
a. - Internal pressure transducer:	☐
b. - Amnioinfusion:	☐
c. - Episiotomy:	☐
d. - Internal version:	☐
4. - Did the mother experience any adverse events during labor and delivery?	Yes ☐
	No ☐
	Unknown ☐
5. - Was the maximum temperature of the mother collected during labor?	Yes ☐
	No ☐
a. - Temperature [nnn.n]:	
b. - Unit:	Celsius (C) ☐
	Fahrenheit (F) ☐
c. - Date:	
d. - Time:	
6. - Was the maximum diastolic blood pressure of the mother collected during labor?	Yes ☐
	No ☐
a. - Diastolic blood pressure [nnn]:	Fixed Unit: mmHg
b. - Date:	
c. - Time:	
7. - Were any concomitant medications given during labor and delivery?	Yes ☐
	No ☐
	Unknown ☐

INSTRUCTIONS:

• For studies where subsequent pregnancies are tracked, the index pregnancies (i.e. enrolled infant) should indicate the Infant PID number and the subsequent pregnancies (i.e. unenrolled infant) should only indicate which fetus/infant this is being completed for.

• When reporting a subsequent pregnancy, leave the Infant PID number field blank and indicate which fetus/infant this is being completed for.

• In the case of multiple births, add a new log line for each fetus/infant.

Congenital anomalies are defined as birth defects, congenital disorders or congenital malformations. They may occur during intrauterine life and can be identified prenatally, at birth or later in life.

If congenital anomalies of the fetus/infant are identified,
report as follows:

• For congenital anomalies identified on a live born enrolled infant, report on the infant participant's Adverse Event Log. In cases of stillbirth/intrauterine fetal demise (IUFD), spontaneous abortion, or induced abortion, report on the maternal participant's Adverse Event Log.

• For congenital anomalies identified for an non-enrolled infant/fetus, report on the maternal participant's Adverse Event Log.

Number of fetuses/infants:
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐

NOTE: If molar pregnancy or false positive, select '0'.

Infant PID number: _____

Indicate which fetus/infant this is being completed for:
- A ☐
- B ☐
- C ☐
- Not applicable ☐

Indicate outcome:
- Live birth ☐
- Stillbirth/Intrauterine fetal demise (IUFD ≥ 20 weeks) ☐
- Spontaneous abortion (< 20 weeks) ☐
- Induced abortion (therapeutic or elective) ☐
- Ectopic pregnancy ☐
- Molar pregnancy ☐
- False positive/No pregnancy ☐

At the time of the pregnancy outcome, were any congenital anomalies identified?
- Yes ☐
- No ☐
- Unknown ☐

Provide date of outcome: _____

Provide a brief narrative of circumstances [200]: _____