To be completed by female participants/subjects only.

Date pregnancy information/outcome obtained (yyyy-mm-dd):

Table Pregnancy Information Table

| Prenatal Test | Date(s) of Testing (yyyy-mm-dd) | Results of Test | Comments |
| --- | --- | --- | --- |
| Ultrasound | Enter data here | Enter data here | Enter data here |
| Amniocentesis | Enter data here | Enter data here | Enter data here |
| Screening for neural tube defects | Enter data here | Enter data here | Enter data here |
| Screening for gestational diabetes before or at 28 weeks | Enter data here | Enter data here | Enter data here |
| Screening for asymptomatic bacteriuria before or at 16 weeks gestation | Enter data here | Enter data here | Enter data here |
| Hepatitis B specific antigen screening at first visit | Enter data here | Enter data here | Enter data here |
| HIV screening at first visit | Enter data here | Enter data here | Enter data here |
| Group B streptococcus screening (GBS) at 35 to 37 weeks | Enter data here | Enter data here | Enter data here |
| Maternal serum alpha fetoprotein | Enter data here | Enter data here | Enter data here |
| Other, specify: | Enter data here | Enter data here | Enter data here |

1. Did/Has the participant/subject experienced any complications during this pregnancy?

Yes  No  Unknown

1. If Yes, specify:
2. Did/Has the participant/subject experienced any infections or illnesses during this pregnancy?

Yes  No  Unknown

1. If Yes, specify:
2. Was prenatal testing for FSHD performed?

Yes  No  Unknown

1. If Yes, specify the result:

## Pregnancy Outcome

1. Was the outcome of the participant’s/subject’s most recent pregnancy a live born infant?

Yes (Skip to Q5)  No (Complete Q4a-c ONLY)  Unknown (STOP, you are finished)

If No, complete the following and then STOP, you are finished:

1. Pregnancy outcome:  Elective termination  Spontaneous abortion (≤ 20 weeks)

Fetal death/stillbirth (> 20 weeks)  Unknown

1. Outcome date (yyyy-mm-dd):
2. Was the fetus normal?  Yes  No  Unknown
   * 1. If No, describe:
3. Delivery type?(Choose only one)

Spontaneous

Induced

Unknown

1. If Induced, specify reason (choose all that apply):
2. Hemorrhage and Placental Complications
3. Hypertension, Preeclampsia or Eclampsia
4. Rupture of Membranes-Premature, Prolonged
5. Maternal Conditions Complicating Pregnancy/Delivery
6. Fetal Conditions Complicating Pregnancy/Delivery
7. Malposition and Malpresentation of Fetus
8. Late Pregnancy
9. Prior Uterine Surgery
10. Other, specify:
11. Delivery route? (Choose only one)

Vaginal  Cesarean section; complete the following:

Specify reason:

Timing of cesarean:  Emergency  Elective  Unknown

1. Delivery modality type:  Breech  Cephalic  Unknown
2. Did the participant/subject experience any complications during labor/delivery?

Yes  No  Unknown

1. If Yes, specify:
2. Did the participant/subject require tocolytic agents during preterm labor?

Yes  No  Unknown

1. If Yes, specify:

## Details of Most Recent Live Birth

1. Birth date (yyyy-mm-dd):
2. Birth sex:  Male  Female  Unknown
3. Birth weight :  ounces  grams
4. Birth length :  inches  centimeters
5. Was the child delivered full-term?  Yes  No  Unknown
6. Indicate gestational age (GA) : weeks
7. 5-minute APGAR score:
8. 10-minute APGAR score:
9. Mother’s weight at the time of birth:  pounds  kilograms
10. Any abnormal fetal diagnostic tests performed during pregnancy?

Yes  No  Unknown

* 1. If Yes, complete the dates of testing and the test results in the following table:

Table Fetal Diagnostic Testing Table

| Date(s) of Testing (yyyy-mm-dd) | Results of Fetal Diagnostic Testing |
| --- | --- |
| Enter data here | Enter data here |

1. Were there any congenital anomalies?  Yes  No  Unknown
2. If Yes, specify:
3. Were there other newborn complications?  Yes  No  Unknown
4. If Yes, specify:
5. Did the newborn experience any abnormalities of placenta or umbilical cord?

Yes  No  Unknown

1. If Yes, specify:
2. Breastfeeding?

Yes  No

1. If Yes, for how many months?
2. If No, specify reason:

## Pregnancy History

1. Has the participant/subject ever been pregnant?

Yes  No (STOP)  Unknown (STOP)

1. Prior pregnancy (both to term and not to term):
2. Number of prior pregnancies:
3. Full-term (≥ 37 weeks) births:
4. Pre-term (< 37 weeks) births:
5. Did a birth defect occur in any previous pregnancy?

Yes  No  Unknown

1. If Yes, specify birth defect:
2. Did a miscarriage (≤ 20 weeks) or stillbirth (> 20 weeks) occur in any previous pregnancy?

Yes  No  Unknown

1. If Yes, in what week of pregnancy did the miscarriage or stillbirth occur? week(s)
2. Has the participant/subject ever had exposure to any of the following during pregnancy? (choose all that apply)
3. Concurrent medication
4. Exposure to X-ray
5. Teratogens
6. Alcohol
7. Smoking
8. Other, specify:

## GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements related to pregnancy and should only be completed by females. It is important to be very explicit and detailed when completing this form to ensure the relevant and accurate data is collected.

## SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Pregnancy most recent live born infant - If 'Yes' is answered, skip to question 2. If 'No' is answered, then complete questions 1a-1c only. If 'Unknown' answered, then Stop.
* Pregnancy outcome type - Choose one. Answer for the female participant/subject only (not the partner). Only answered if No was answered for "Was the outcome of the participant's/subject's most recent pregnancy a live born infant?". Complete this question, outcome date, and was the fetus normal and then stop completing the form.
* Delivery by cesarean reason – Answer only if Cesarean was the delivery route.
* APGAR five minute score – Record the score (0 - 10 points, inclusive)
* APGAR ten minute score - Record the score (0 - 10 points, inclusive)