14. CHART ABSTRACTION FOR SELECT SUBSEQUENT PREGNANCIES

14.1 Introduction

The nuMoM2b-Heart Health Study (nuMoM2b-HHS) protocol specifies that, if the participant agrees, medical records are requested for selected CVD-related hospitalizations and procedures reported on interval contacts and during the in-clinic maternal interview and for participants who self-reported multiple gestation pregnancies or adverse pregnancy outcomes on interval contacts (see Chapters 9 (Interval Contacts) and 10 (2-5 Year Postpartum Clinic Visit) of the Manual of Operations for details on when and how to request access to these records).

This chapter focuses on chart abstraction from the delivery records that are requested for participants who, during an interval contact, report one or more completed pregnancies subsequent to nuMoM2b involving multiple gestation or an adverse pregnancy outcome and agree that the site may request the medical records (from conception through 14 days postpartum) related to that pregnancy. The screening for multiple gestation and adverse pregnancy outcomes (and consent to request medical records, as indicated) is performed separately during interval contacts for each completed pregnancy subsequent to the nuMoM2b.

In this context, the self-reported adverse pregnancy outcomes of interest are: preeclampsia (including HELLP and eclampsia), hypertension, or high blood pressure (including chronic hypertension) during the pregnancy; preterm birth (<37\(0\) weeks gestation); premature labor or ruptured membranes requiring treatment (before \(37^0\) weeks of pregnancy); singleton baby weight less than 2500 gm (5 lbs, 6 oz), gestational diabetes mellitus (GDM); stillbirth; and pregnancy loss <20\(0\) weeks gestation.

Self-report information for multiple gestation and adverse pregnancy outcomes for each completed pregnancy is recorded in Sections E and E2 of Form TXX (Interval Contact Form). The data entry program checks the responses as they are entered and if the pregnancy meets criteria for chart abstraction the interviewer is prompted to ask the participant (or the participant is asked directly by the data entry program, if completed online) for permission to send the participant a medical release form to sign and return and for the name of the facility where the delivery occurred. For participants completing Form TXX online, pregnancies meeting criteria for chart abstraction are identified by the site using a periodic DCAC report that identifies all qualifying pregnancies.

For each completed pregnancy meeting the selection criteria, and for which a signed medical release form has been received, data are abstracted from the records of the delivery hospitalization (or records from the end of the pregnancy) and any readmissions to the delivery hospital within 14 days postpartum and any other available records from during the relevant pregnancy. The information to be abstracted includes the occurrence of and related information for the following APOs: preeclampsia, gestational hypertension, spontaneous and indicated preterm birth, birth weight and gestational age at delivery (for calculation of SGA), GDM, stillbirth, and pregnancy loss <20\(0\) weeks gestation. During chart review, the abstractor uses nuMoM2b definitions to the extent possible; otherwise, the best obstetrical diagnosis is recorded. The site PI adjudicates any discrepancies. The extent to which nuMoM2b definitions can be applied is documented in subsequent sections of this chapter.
14.2 nuMoM2b Definitions Pertinent to Chart Abstraction for Subsequent Pregnancies and Adaptations for the Heart Health Study

14.2.1 Introduction

For the prospective nuMoM2b study, abstractors had access to data from nuMoM2b visits, prenatal care records, records from antepartum hospitalizations, delivery records, and records from hospitalizations through 14 days postpartum. For the nuMoM2b-HHS, we are requesting the same records, but realize that site staff may only obtain records from the delivery hospitalization (discharge summary, labor and delivery notes, and laboratory results) and readmissions through 14 days postpartum (discharge summary, laboratory results, and blood pressures). Given that records from prenatal visits, antenatal hospitalizations, and postpartum admissions will not be available in some cases, chart abstractors are instructed to use nuMoM2b definitions to the extent possible; otherwise the best obstetrical diagnosis is abstracted: Some of the pertinent modifications for nuMoM2b-HHS are included in italics in the specifications below.

A selected subset of nuMoM2b definitions pertinent to chart abstraction for subsequent pregnancies is given in the Sections 14.2.2 through 14.2.7 below. Among these, the definition of severe preeclampsia has been edited to remove some ambiguity in the wording of the original definition. Some minor edits have also been applied for purposes of clarity (e.g., “[nuMoM2b] Project EGA” for “Project EGA”). References to literature cited in the definitions are found in Section 14.2.8.

14.2.2 nuMoM2b Project Estimated Date of Delivery (used to calculate nuMoM2b Project Estimated Gestational Age)

The “[nuMoM2b] project estimated date of delivery” (EDD) is determined in accordance with the following priority levels, and is used to determine the “[nuMoM2b] project estimated gestational age” (EGA) at enrollment. Once determined for an individual subject, the “project EDD” is not revised. It is critical to take special care in dating the pregnancy of each participant to the study. The [nuMoM2b] project EDD is determined as follows:

1. In the absence of a “sure” last menstrual period (LMP) or in vitro fertilization or artificial insemination, the “project ultrasound” is used to determine the [nuMoM2b] project EDD. The project EDD is determined based on the fetal crown-rump length (CRL) measurement. The presence of a gestational sac is not sufficient. CRL is the length of the fetus from the top of the head (crown) to the bottom of the buttocks (rump).

The CRL, in centimeters and in a range of prediction from 0-12 centimeters (0-120 millimeters), is used to compute an estimated gestational age in days on the ultrasound date as follows:

\[
\text{exp} [1.684969 + (0.315646 \times \text{CRL}) - (0.049306 \times \text{CRL} \times \text{CRL}) + (0.004057 \times \text{CRL} \times \text{CRL} \times \text{CRL}) - (0.000120456 \times \text{CRL} \times \text{CRL} \times \text{CRL} \times \text{CRL})].
\]

This result may be obtained from an ultrasound report, but the calculation is also available on the nuMoM2b project website.

The project EDD is then computed as follows:

\[
\text{Project ultrasound date} + (280 – \text{ultrasound estimated gestational age in days})
\]

2. If the participant has a “sure” LMP, the project ultrasound CRL measurement is used to confirm the project LMP. An LMP is labeled “sure” when the woman is sure of the LMP date within plus or minus 3 days, she has a regular 24-35 day cycle, and she is not on oral contraceptives at the time of conception.

If the project ultrasound confirms a sure LMP (using the criteria delineated in Table 14-1 below), the sure LMP is used to establish the [nuMoM2b] project EDD as follows.

\[
\text{Project EDD} = \text{LMP} + 280 \text{ days}
\]

If the project ultrasound does not confirm the sure LMP (criteria delineated in Table 14-1 are not met), then the project ultrasound is used to determine the [nuMoM2b] project EDD (see number 1 above).

Calculation for a project EDD from LMP, with checks against ultrasound results, is available on the nuMoM2b project website.

<table>
<thead>
<tr>
<th>Table 14-1</th>
<th>Cutoffs for Ultrasound Confirmation of Project EGA based on a sure LMP or Artificial Insemination</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gestational age at first ultrasound by LMP</strong></td>
<td><strong>Project ultrasound agreement with LMP</strong></td>
</tr>
<tr>
<td>&lt; 7(^{th}) weeks</td>
<td>±3 days</td>
</tr>
<tr>
<td>7(^{th}) to 7(^{th}) weeks</td>
<td>±4 days</td>
</tr>
<tr>
<td>8(^{th}) to 10(^{th}) weeks</td>
<td>±5 days</td>
</tr>
<tr>
<td>11(^{st}) to 12(^{th}) weeks</td>
<td>±6 days</td>
</tr>
<tr>
<td>13(^{th}) weeks or more</td>
<td>±7 days</td>
</tr>
</tbody>
</table>

3. If the pregnancy was conceived by \textit{in vitro} fertilization (IVF), one of the processes by which the egg is fertilized by sperm outside the womb and then returned to the woman’s uterus, the [nuMoM2b] project EDD is determined as follows, regardless of correlation with project LMP.

For a “3-day” fresh/frozen embryo replacement date:

\[
\text{Project EDD} = \text{embryo replacement date} + 263 \text{ days}
\]

For a “5-day” fresh/frozen embryo replacement date:

\[
\text{Project EDD} = \text{embryo replacement date} + 261 \text{ days}
\]

Calculation for a project EDD from IVF dating, with checks against ultrasound results, is available on the nuMoM2b project website.
4. If the pregnancy was conceived using artificial insemination (AI), the process by which sperm is placed into the reproductive tract of the woman by means other than intercourse, the [nuMoM2b] project EDD is determined as follows, regardless of correlation with project LMP:

   Project EDD = date of insemination + 266 days

If the [nuMoM2b] project ultrasound does not confirm the project EDD and EGA based on insemination date, then the project EDD and EGA is determined based on the project ultrasound.

Calculation for a project EDD from AI, with checks against ultrasound results, is available on the nuMoM2b project website.

**Note:** For the nuMoM2b-HHS, much of the information required for these calculations will not be available and ultrasounds are unlikely to have been done by certified staff. Therefore, we will use the clinical estimated date of delivery (EDD) and estimated gestational age (EGA) given in the delivery records related to the pregnancy.

### 14.2.3 Pregnancy Loss Before 20 Completed Weeks of Gestation, Stillbirth, and Live Birth

1. **Abortion** is defined as delivery of a liveborn or fetus suffering fetal death for any cause before 20⁰ weeks.
   a. **Elective abortion** is defined as induced delivery or dilatation and curettage/evacuation of a fetus before 20⁰ weeks project estimated gestational age (project EGA) in the absence of a diagnosis of preterm contractions or labor, PROM, membrane prolapse, or fetal death. **Note:** For the nuMoM2b-HHS, terminations will be specified as elective (no medical indication) or indicated (medical indication for termination). The conditions associated with the pregnancy loss will be noted, but the specific indication for a termination will not be collected.
   b. **Spontaneous abortion** is defined as fetal death leading to vaginal delivery or dilatation and curettage/evacuation, or spontaneous expulsion of a liveborn fetus due to any cause before 20⁰ weeks project EGA. Additionally, any abortion not meeting the criteria for “elective abortion” delineated above will be considered a spontaneous abortion (including a documented vanishing twin).

2. **Stillbirth** is defined as a fetal death at a project EGA of 20⁰ weeks or greater with Apgar scores of 0/0 at 1, 5, and 10 minutes with no other signs of life by direct observation.

3. **Live birth** is defined as an infant of at least 20⁰ weeks gestational age that demonstrates signs of life by direct observation after birth (movement, 1 or 5 minute Apgar scores >0), regardless of attempts at resuscitation and subsequent Apgar scores.

### 14.2.4 Preterm Birth

1. **Preterm birth** is defined as delivery of a live born or stillborn infant for any cause between 20⁰ weeks and 36⁶ weeks project EGA.
   a. For this study [nuMoM2b], **spontaneous preterm birth** is defined as delivery occurring subsequent to spontaneous onset of preterm labor or preterm Premature Rupture of the
Membranes (preterm PROM) or fetal membrane prolapse, regardless of subsequent labor augmentation or cesarean delivery.

1) For this [the nuMoM2b] study, a primary diagnosis of preterm labor is defined as spontaneous uterine contractions (more than 6 contractions per hour documented by tocodynamometry or by maternal history), with onset before membrane rupture, and that lead to delivery.

If the participant delivers as a result of a different primary diagnosis, she may also have a secondary diagnosis of preterm labor that ultimately does or does not lead to delivery. A secondary diagnosis of preterm labor requires more than 6 contractions per hour documented by tocodynamometry or by maternal history plus:

a) documented cervical change (at least 1 cm dilation or 1 cm effacement) during the current admission OR

b) cervix dilated >2 cm OR cervical effacement >80% on admission for contractions.

The presence of uterine contractions in the absence of the either criterion will result in a secondary diagnosis of preterm contractions.

2) For this [the nuMoM2b] study, a primary diagnosis of premature rupture of the membranes (PROM) is defined as spontaneous rupture of the membranes before the onset of contractions, regardless of subsequent labor augmentation or cesarean delivery.

Rupture of the membranes requires a documented clinical suspicion for this diagnosis based on clinical history and/or ultrasound accompanied by any one (1) of the following:

a) Visible leaking of amniotic fluid from the cervix

b) Presence of vaginal indigo carmine after intra-amniotic installation; or

c) Any two (2) of the following:

   Pooling of fluid in the vaginal vault.

   Positive Nitrazine test

   Positive Ferning of dried vaginal fluid observed microscopically

   Positive biochemical test for PROM (e.g., Amnisure, alpha-microglobin, MSAFP, HCG, IFN).

3) For this [the nuMoM2b] study, a primary diagnosis of membrane prolapse is defined by spontaneous descent of the fetal membranes to or past the external cervical os in the absence of uterine contractions (more than 6 contractions per hour documented by tocodynamometry or by maternal history), PROM, maternal fever or uterine tenderness, chorioamnionitis (clinical or amniocentesis diagnosis), or abruptio placentae, regardless of the placement of a cervical suture (cerclage).

Women who deliver after cerclage placement for a short cervix or membrane prolapse or funnel that does not reach the external cervical os do not meet the criteria for the diagnosis of membrane prolapse. The indication for delivery under this circumstance will be the ultimate precipitating cause of delivery (e.g., preterm labor, PROM, chorioamnionitis, abruptio placentae, preeclampsia, etc.)

4) Women delivering a live born or stillborn infant for any cause between 20⁰ weeks and 36⁶ weeks project EGA and who do not meet any of the above criteria for
spontaneous preterm birth will be categorized as spontaneous preterm birth otherwise unspecified.

b. For this [the nuMoM2b] study, indicated preterm birth is defined as delivery following induction or cesarean delivery at <37\textsuperscript{0} weeks gestation for one or more conditions that the woman’s caregiver determines to threaten the health/life of the mother or fetus. The caregiver’s primary diagnoses associated with indicated preterm birth will be categorized as follows (confirmatory criteria are listed subsequently):

1) **Pregnancy associated hypertension:** If this diagnosis is made as an indication for delivery, the documented category of hypertension leading to delivery will be specified as follows:
   a) Pre-eclampsia
      - Mild
      - Severe
      - HELLP syndrome
      - Eclampsia
      - Atypical
      - Unspecified
   b) Gestational hypertension

**NOTE:** For the nuMoM2b-HHS, the categories for pregnancy associated hypertensive disease are:
   - Gestational hypertension
   - Mild preeclampsia
   - Severe preeclampsia
   - Superimposed preeclampsia
   - Preeclampsia, unspecified
   - Eclampsia
   - HELLP syndrome
   - Incomplete HELLP syndrome
   - Unspecified

2) **Fetal growth restriction (FGR):** Participants delivered for a diagnosis of “small for gestational age (SGA)” or “intrauterine growth restriction (IUGR)” will be considered to meet the criteria for “fetal growth restriction (FGR)” as the indication for delivery.

3) **Abruptio placentae:** Participants delivered for a diagnosis of abruptio placentae will be considered to meet the criteria for this indication unless the diagnosis is preceded by a diagnosis of preterm labor or PROM prior to the onset of vaginal bleeding.
4) **Placenta previa**: Participants delivered for a diagnosis of placenta previa will be considered to meet the criteria for this indication regardless of the presence of vaginal bleeding at the time of delivery.

5) **Chorioamnionitis**: Participants delivered for a diagnosis of chorioamnionitis will be considered to meet the criteria for this indication unless the diagnosis is preceded by a diagnosis of preterm labor or PROM prior to the diagnosis of chorioamnionitis.

6) **Abnormal fetal testing**: Participants delivered for a diagnosis of abnormal fetal testing will be considered to meet the criteria for this indication, and the primary indication for fetal testing will be specified.

7) **Congenital fetal anomaly(ies)**: Participants delivered for a diagnosis of fetal anomaly(ies) or malformation(s) or birth defect(s) will be considered to meet the criteria for this indication, and the fetal abnormality leading to delivery will be specified.

8) **Maternal medical condition(s)**: Participants delivered for a diagnosis of a maternal medical condition will be considered to meet the criteria for this indication and the medical condition leading to delivery will be categorized as follows.
   a) Chronic hypertension
   b) Diabetes
   c) Cardiac disease (specified)
   d) Cancer (specified)
   e) Transplant (specified)
   f) Cholestasis
   g) Systemic lupus erythematosus
   h) Asthma
   i) Prior uterine surgery (specified).

9) **Other indicated preterm birth**: Participants undergoing an indicated preterm birth for a documented reason that is not delineated above will meet the criteria for “other indicated preterm birth,” and the indication will be specified.

10) **No documented indication**: Participants induced or delivered electively by cesarean delivery preterm and who do not have an indication for preterm delivery specified in their medical record will be considered to have “no documented indication for preterm birth.”

### 14.2.5 Hypertensive/Proteinuric Outcomes

1. The diagnosis of **hypertension** will be made if the blood pressure is \( \geq 140 \text{ mmHg systolic or } \geq 90 \text{ mmHg diastolic} \) on two (2) occasions at least 6 hours apart, or has a single elevated blood pressure of \( \geq 140 \text{ mmHg systolic or } \geq 90 \text{ mmHg diastolic} \) with subsequent antihypertensive medication therapy. Blood pressures recorded during the second stage of labor will be excluded from consideration when evaluating the medical record for hypertension.
   a. **Severe hypertension** requires the qualifying blood pressures, or the single elevated blood pressure with subsequent antihypertensive medication therapy, to have systolic pressure \( \geq 160 \text{ mmHg} \) or diastolic pressure \( \geq 110 \text{ mmHg} \).
b. **Mild hypertension** is diagnosed if there is hypertension and the criteria for severe hypertension are not met. 

2. The diagnosis of **chronic hypertension** will be made if the patient meets the criteria for hypertension before pregnancy or before 20⁰ weeks gestation.

3. **Proteinuria:** Healthy individuals excrete <150 mg of urinary protein in 24 hours (Longo, et al., 2011). Thus 24-hour excretion ≥150 mg indicates proteinuria. Preeclamptic levels of proteinuria are defined as ≥300 mg in 24 hours (ACOG Practice Bulletin #33, 2002). The 24-hour urine collection is the definitive test and supersedes all urinary dipstick values and protein-creatinine ratios during a given time frame. Operational definitions may vary regarding the use of dipstick values or urinary protein-creatinine ratios when 24-hour urine measurements are not available.

In nuMoM2b, proteinuria diagnosed at baseline (prior to the current pregnancy or during the current pregnancy prior to 20⁰ weeks project EGA) must be documented with a 24-hour urine quantification, not by protein-creatinine ratio or spot urinary dipstick testing. The diagnosis of proteinuria during this time frame will be made if any total 24-hour urine protein excretion value is ≥150 mg. Those so diagnosed will be further divided into those for whom the highest baseline 24-hour urine protein value is ≥150 and <300 mg versus ≥300 mg.

For the time period ≥20⁰ weeks project EGA through 14 days postpartum, the diagnosis of preeclamptic proteinuria will be made if any total 24-hour urine protein excretion value is ≥300 mg. However, if no 24-hour urine is available during this time frame, then preeclamptic proteinuria can be diagnosed if there is at least one urinary protein value ≥2+ on dipstick or at least one protein-creatinine ratio ≥0.30 (300mg/g).

Also for the time period ≥20⁰ weeks project EGA through 14 days postpartum, if there is no new-onset hypertensive disorder of pregnancy, the diagnosis of isolated proteinuria will be made if any total 24-hour urine protein excretion value is ≥150 mg. Dipstick or protein-creatinine ratio values will not be used. New-onset hypertensive disorders of pregnancy include gestational hypertension, preeclampsia (mild, severe, or superimposed), HELLP syndrome, and eclampsia (definitions are provided below).

Thus we make the following definitions regarding proteinuria:

**Baseline Proteinuria:** Proteinuria occurring prior to the current pregnancy or before 20⁰ weeks project EGA in the current pregnancy, documented by at least one total 24-hour urine protein excretion value ≥150 mg.

a. **Baseline proteinuria ≥150 and <300** indicates that there is baseline proteinuria, but the criteria for baseline proteinuria ≥300 have not been met.

b. **Baseline proteinuria ≥300** indicates that there is baseline proteinuria and at least one total 24-hour urine protein excretion value is ≥300 mg prior to the current pregnancy or before 20⁰ weeks project EGA during the current pregnancy.

**Preeclamptic Proteinuria:** The diagnosis of preeclamptic proteinuria will be made if, at ≥20⁰ weeks project EGA through 14 days postpartum, there is at least one total 24-hour urine protein excretion value that is ≥300 mg, or if there is ≥2+ proteinuria on dipstick or a protein-creatinine ratio ≥0.3 (300mg/g) if no 24-hour urine is available in this time frame.

a. **Mild preeclamptic proteinuria** is defined as 24-hour urine total protein excretion value ≥300 mg and <5,000 mg.

b. **Severe preeclamptic proteinuria** is defined as a 24-hour urine total protein excretion value ≥5,000 mg.
Severity of preeclamptic proteinuria will not be categorized if a 24-hour urine result is not available.

**Isolated Proteinuria:** The diagnosis of isolated proteinuria will be made if, at ≥20⁰ weeks postpartum, there is at least one total 24-hour urine protein excretion value that is ≥150 mg and there is not a diagnosis of a new onset hypertensive disorder of pregnancy (gestational hypertension, preeclampsia, HELLP syndrome, or eclampsia).

4. **Preeclampsia:** Preeclampsia is defined by events occurring through 14 days postpartum. Definitions below are provided for four groups of participants defined by hypertension and proteinuria status before 20⁰ weeks gestation. The two groups with pre-existing proteinuria are subgrouped according to the magnitude of the baseline proteinuria as <300 or ≥300.

   **Group I – Women who do not have pre-existing hypertension or proteinuria before 20⁰ weeks gestation.**
   
   The diagnosis of preeclampsia requires the development of new onset hypertension at ≥20⁰ week’s gestation plus one of the following:
   
   a. preeclamptic proteinuria,
   
   b. thrombocytopenia (<100,000 /mm³), or
   
   c. pulmonary edema.

   **Group II – Women with pre-existing proteinuria and normal blood pressure before 20⁰ weeks gestation.**

   **Group IIa – Baseline proteinuria <300.**
   
   The diagnosis of preeclampsia requires the development of new onset hypertension at ≥20⁰ week’s gestation plus one of the following:
   
   a. preeclamptic proteinuria,
   
   b. thrombocytopenia (<100,000 /mm³), or
   
   c. pulmonary edema.

   **Group IIb – Baseline proteinuria ≥300.**
   
   The diagnosis of preeclampsia requires the development of new onset hypertension at ≥20⁰ week’s gestation plus one of the following:
   
   a. sudden increase in proteinuria (5 times the base-line value, or 2 times a base line value of ≥5,000 mg/24-hours).
   
   b. thrombocytopenia (<100,000 /mm³),
   
   c. serum aspartate aminotransferase (AST) concentration ≥100 IU/L,
   
   d. severe headache, or
   
   e. epigastric pain.
Group III – Women with pre-existing hypertension but no proteinuria before 20\(^0\) weeks gestation.

The diagnosis of preeclampsia requires the presence of one of the following:

a. preeclamptic proteinuria, or
b. thrombocytopenia (<100,000 /mm\(^3\)).

Group IV – Women with both pre-existing hypertension and proteinuria before 20\(^0\) weeks gestation.

Group IVa – Baseline proteinuria <300.

The diagnosis of preeclampsia requires the presence of one of the following:

a. preeclamptic proteinuria, or
b. thrombocytopenia (<100,000 /mm\(^3\)).

Group IVb – Baseline proteinuria ≥300.

The diagnosis of preeclampsia requires one or more of the following:

a. worsening hypertension, as shown by two diastolic blood pressures ≥110 mmHg taken four hours apart in the week before delivery plus one of the following:
   - severe headache,
   - epigastric pain, or
   - sudden increase in proteinuria (5 times the base-line value, or 2 times a baseline value of ≥5,000 mg/24 hours);

b. thrombocytopenia (<100,000 /mm\(^3\)); or

c. serum aspartate aminotransferase (AST) ≥100 IU/L.

Women will also be determined to have preeclampsia if they have a diagnosis of either of the following during pregnancy through 14 days postpartum:

a. Eclampsia defined as a seizure without another known cause during pregnancy through 14 days postpartum; or

b. HELLP syndrome, defined as:
   1) Hemolysis evidenced by
      - serum total bilirubin ≥1.2 mg/dL (20 µmol/L),
      - serum lactate dehydrogenase (LDH) ≥600 IU/L, or
      - hemolysis on peripheral smear; AND
   2) Serum aspartate aminotransferase (AST) ≥100 IU/L; AND
   3) Thrombocytopenia (<100,000 /mm\(^3\))

For women who do not have pre-existing hypertension before 20\(^0\) weeks gestation and either do not have baseline proteinuria (Group I) or have baseline proteinuria <300 (Group IIa):

Mild preeclampsia is diagnosed if there is preeclampsia and the diagnostic criteria for severe preeclampsia are not met.
Severe preeclampsia is diagnosed if there is a diagnosis of preeclampsia and one or more of the following:

- new onset severe hypertension at ≥20⁰ weeks gestation,
- new onset of severe proteinuria at ≥20⁰ weeks gestation,
- severe headache,
- epigastric pain,
- pulmonary edema,
- eclampsia,
- new onset thrombocytopenia (<100,000 /mm³) at ≥20⁰ weeks gestation,
- HELLP syndrome,
- oliguria (24-hour urine volume <500 ml), or
- fetal growth restriction (antenatal diagnosis) without other identifiable cause.

If one or more laboratory values (platelet count, 24-hour urine volume, serum total bilirubin, serum LDH, peripheral smear for hemolysis) are missing, AND none of the other criteria for severe preeclampsia have been met, the preeclampsia will be classified as mild.

Progression from mild to severe preeclampsia can occur, so both conditions can occur in a single participant.

5. **Superimposed Preeclampsia** will be diagnosed if there is a history of chronic hypertension before 20⁰ weeks gestation or there is baseline proteinuria ≥300 (i.e., women in Group IIb, III, or IV), and there is an additional diagnosis of preeclampsia. For superimposed preeclampsia, subclassification by severity (mild, severe) is not defined.

6. The diagnosis of *Gestational Hypertension* will be made if there is new onset hypertension after 20⁰ weeks gestation and the criteria for preeclampsia are not met, regardless of the severity of hypertension. (This diagnosis can only be made for women in Group I or II.)

The following table shows possible hypertensive/proteinuric conditions at ≥20⁰ week’s gestation according to baseline hypertension and proteinuria status:

<table>
<thead>
<tr>
<th>Baseline hypertension/proteinuria groups (&lt;20 weeks gestation)</th>
<th>Possible new hypertensive/proteinuric conditions (≥20 weeks gestation)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
<td><strong>HTN</strong></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>I</td>
<td>No</td>
</tr>
<tr>
<td>II</td>
<td>a</td>
</tr>
<tr>
<td></td>
<td>b</td>
</tr>
<tr>
<td>III</td>
<td>Yes</td>
</tr>
<tr>
<td>IV</td>
<td>a</td>
</tr>
<tr>
<td></td>
<td>b</td>
</tr>
</tbody>
</table>

HTN=hypertension, PE=preeclampsia.

14.2.6 Fetal Growth Restriction (FGR)

It is recognized that the antenatal diagnosis of fetal growth restriction may not be confirmed after delivery, and that infants with FGR may not be diagnosed before birth.
1. Before birth, the prenatal diagnosis of FGR will be based on the caregiver’s clinical diagnosis. The criteria used by the patient’s caregiver to make the diagnosis will be specified.

2. After birth, the postnatal diagnosis of FGR will be made based on measured birth weight for gestational age.

Note: In nuMoM2b-HHS, we will collect the infant’s birth weight and the estimate of gestational age as noted in Section 14.2.2 above. We will not be collecting a caregiver’s clinical diagnosis of FGR except as it may be recorded on Form P5B as the clinician’s primary reason for delivery or a maternal or obstetric condition known to be present during labor and delivery.

14.2.7 Diabetes Mellitus

1. Clinical diagnoses

For the purpose of this study, the “diagnosis” of diabetes mellitus and/or gestational diabetes will be abstracted from the patient record (Form P5D, Subsequent Pregnancy – Labor, Delivery, and Postpartum: Section D). For women with a diagnosis of diabetes mellitus made before the onset of pregnancy, glucose tolerance testing performed prior to the initial diagnosis will not be required as this information will often be remote and unavailable.

The White’s classification will be applied (Form P5B, Subsequent Pregnancy – Pregnancy, Delivery, and Postpartum: Section D, question 2). A diagnosis of gestational diabetes will be given to women with a new diagnosis of diabetes during the pregnancy being reported, regardless of insulin requirement or subsequent postpartum glucose intolerance. Women with gestational diabetes will be classified as “A1” for those not requiring insulin or oral hypoglycemic therapy or “A2” for those requiring insulin or oral hypoglycemic therapy. Conventional criteria for class B and greater will apply. Where multiple White’s classifications are documented, the final classification will be adjudicated by a local nuMom2b-HHS investigator.

2. Evaluations of glucose intolerance

There is not a unified approach to the diagnosis of diabetes or gestational diabetes among the nuMoM2b-HHS centers. For nuMoM2b, diagnostic plasma glucose values were collected by chart review for each participating NuMom2b study subject on nuMoM2b Form CLA, Prenatal Labs: Section E, questions 2 through 7. These may include:

- Fasting plasma glucose tests collected at or prior to a diagnosis of diabetes,
- “Casual” (random) plasma glucose tests collected at or prior to a diagnosis of diabetes,
- 50 gram glucose screen,
- 3-hour 100 gram glucose tolerance test,
- 2-hour 75 gram glucose tolerance test
- Hemoglobin A1c, if done.

Note: For nuMoM2b-HHS, these lab values will not be recorded on the forms, but should be used to make diagnoses if they are available. If lab values are
not available, diagnoses will come from clinical notations in the available medical record. Using this information, “diagnoses” of diabetes mellitus or gestational diabetes can be assigned according to the Carpenter and Coustan criteria (Carpenter & Coustan, 1982; ACOG Practice Bulletin #30, 2001), the 2003 Expert Committee on the Diagnosis and Classification of Diabetes Mellitus report (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003), or the 2010 International Association of Diabetes and Pregnancy Study Groups Consensus Panel criteria (International Association of Diabetes and Pregnancy Study Groups Consensus Panel et al., 2010) for further analyses and comparisons. The following are definitions of diabetes and gestational diabetes specific to each set of criteria. In each, gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. 

**Carpenter and Coustan Criteria** (Carpenter & Coustan, 1982; ACOG Practice Bulletin #30, 2001)

Gestational diabetes is diagnosed in women with plasma glucose values that satisfy **two or more** of the following criteria during a 100 gram load diagnostic 3-hour glucose tolerance test:

- Fasting \( \geq 95 \text{ mg/dl} \)
- One hour \( \geq 180 \text{ mg/dl} \)
- Two hour \( \geq 155 \text{ mg/dl} \)
- Three hour \( \geq 140 \text{ mg/dl} \)

**2003 Expert Committee on the Diagnosis and Classification of Diabetes Mellitus criteria** (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003)

Gestational diabetes is diagnosed in women with plasma glucose values that satisfy **two or more** of the following criteria during a 100 gram load diagnostic 3-hour glucose tolerance test:

- Fasting \( \geq 95 \text{ mg/dl} \)
- One hour \( \geq 180 \text{ mg/dl} \)
- Two hour \( \geq 155 \text{ mg/dl} \)
- Three hour \( \geq 140 \text{ mg/dl} \)

**OR two or more** of the following criteria during a 75 gram load diagnostic 2-hour glucose tolerance test:

- Fasting \( \geq 95 \text{ mg/dl} \)
- One hour \( \geq 180 \text{ mg/dl} \)
- Two hour \( \geq 155 \text{ mg/dl} \)

In addition to those women with a history of diabetes mellitus prior to pregnancy, diabetes is diagnosed in women without such a history if there is a fasting plasma glucose level \( \geq 126 \text{ mg/dl} \) or a casual (random) plasma glucose value \( \geq 200 \text{ mg/dl} \) that is confirmed on a subsequent day.
**International Association of Diabetes and Pregnancy Study Group Consensus Panel criteria** (International Association of Diabetes and Pregnancy Study Groups Consensus Panel et al., 2010)

Gestational diabetes is diagnosed in women with plasma glucose values that satisfy **one or more** of the following criteria during a 75 gram load diagnostic 2-hour glucose tolerance test:

- **Fasting** ≥ 92 mg/dl
- **One hour** ≥ 180 mg/dl
- **Two hour** ≥ 153 mg/dl

Gestational diabetes is also diagnosed in women without a pre-pregnancy diagnosis of diabetes who have a fasting plasma glucose value ≥ 92 mg/dl but < 126 mg/dl at any gestational age prior to a diagnosis of diabetes.

In addition to those women with a history of diabetes mellitus prior to pregnancy, diabetes is diagnosed in women without such a history if there is a fasting plasma glucose level ≥ 126 mg/dl or a hemoglobin A1c value ≥ 6.5% using a DCCT/UKPDS (Diabetes Control and Complications Trial / UK Prospective Diabetes Study) standardized assay at any gestational age.

### 14.2.8 References


### 14.3 Identifying Sources of Records

During interval contacts, participants provide self-reported outcomes for pregnancies subsequent to the nuMoM2b study. If a participant self-reports that she had a multiple gestation or adverse pregnancy outcome (defined for purposes of chart abstraction as live birth less than 37th weeks estimated gestational age [EGA], stillbirth, pregnancy loss less than 20th weeks EGA, hypertensive disorder, gestational diabetes, or singleton baby weight less than 2500 gm [5 lbs, 6 oz]), the data entry program prompts the interviewer to ask the participant (or the participant is
asked directly by the data entry program, if completed online) for permission to access records related to the delivery and any readmissions within 14 days after delivery and (if the participant agrees) for the name of the facility where the delivery occurred (see Section E of the TXX form documented in Chapter 9 of the Manual of Operations). Site staff then mail a written authorization for release of the medical records from delivery and any readmissions within 14 days after delivery to the participant (or present it to the participant during a 2-5 Year postpartum clinic visit). The site follows up as necessary to obtain the written release for these records.

As the chart abstraction forms were being finalized, it has become clear that information from prenatal records and antepartum hospitalizations is needed to optimally complete Form P5C, Subsequent Pregnancy – Maternal Hypertensive Disorders. Therefore, these records should also be acquired when feasible.

The DCAC provides a report listing all the study IDs for which a site needs to obtain a medical release form. Participants meeting the above criteria (multiple gestation or APO and agreement to provide access to medical records) are identified in the APO column of the summary. More detailed information related to the event is contained on subsequent pages of the report. Those participants who completed the interval contact form online who meet the above criteria are identified from this report.

14.4 Accessing Medical Records

14.4.1 Introduction

Medical records are organized and accessed differently in each facility. Each site should determine the best way to access medical records, verify that the records requested are for the correct participant and pregnancy, and locate the specific items to be extracted within those records. Site staff should document the specific procedures that will enable efficient and consistent chart abstraction in the “Local Rules for Chart Abstraction.” For sites accessing records through multiple hospitals or other delivery facilities, it may be necessary to document these procedures for each facility.

14.4.2 Medical Records for Pregnancy Chart Abstraction

For each identified pregnancy that meets selection criteria, and for which medical release form(s) have been provided, coordinators request the following records from the delivery hospitalization:

- the discharge summary,
- labor and delivery notes,
- vital signs,
- laboratory results, and
- other relevant records.

For any rehospitalizations within 14 days after that delivery, coordinators request the following records:
• the discharge summary,
• laboratory results, and
• vital signs (i.e., blood pressures).

For pregnancy losses before 20\textsuperscript{th} weeks gestation, there may not have been an admission to the hospital or labor and delivery, e.g., when there is dilatation and curettage/evacuation. In these cases,

• appropriate records dated around the time of the loss should be sought from physician’s offices or outpatient clinics.

Records may be available for access through local hospital medical records systems or may be obtained and maintained in the participant folders described in the next section.

For stillbirths,

• the autopsy report should be requested in addition to the above records.

Optimal completion of Form P5C, Subsequent Pregnancy – Maternal Hypertensive Disorders, requires access to

• prenatal records (vital signs, laboratory results, and care giver notes at a minimum) and
• records from antenatal hospitalizations.

Therefore, these records should also be acquired when feasible.

Section A of Form P5A, Subsequent Pregnancy – Outcome Summary, provides a place to record which of the participant’s medical records were available when the chart abstraction forms for a pregnancy are completed.

**14.4.3 Storing Medical Records Files**

Sites generally maintain a study folder for each participant including copies of signed consent forms and medical records release forms. This folder may be paper or a combination of paper and electronic documents. That is, site staff may opt to maintain these folders in hard copy in a secure location (locked filing cabinet). However, a coordinator may scan the records and systematically file the scanned images in a secure, easy to access manner as appropriate for the site. Each coordinator needs to determine how best to organize and store documents for the local setting.

**14.4.4 Protecting Identifying Information on Charts and Electronic Files**

Initially hard copy / electronic files of medical records include identifying information and must be kept in a secure location at all times. These records need to be destroyed or have all identifiers removed when study investigators no longer require access to them, unless local IRB regulations specify different requirements and these were incorporated into the consent form. Timing and procedures for the destruction of identifying information on various documents will be specified by the nuMoM2b-HHS Steering Committee during the course of the study.
14.5 Subsequent Pregnancy Chart Abstraction Forms

The forms used for chart abstraction of subsequent pregnancies during the nuMoM2b-HHS are as follows:

- P5A - Subsequent Pregnancy – Outcome Summary
- P5B - Subsequent Pregnancy – Labor, Delivery, and Postpartum
- P5C - Subsequent Pregnancy – Maternal Hypertensive Disorders
- P5D - Subsequent Pregnancy – Loss <20\(^0\) Weeks EGA
- P5E - Subsequent Pregnancy – Stillborn Workup
- P5F - Subsequent Pregnancy – Record of Adjudication for Maternal Hypertensive Disorder

Form P5A is completed for all chart abstracted pregnancies. Instructions for identifying additional forms to be completed are given in Section 14.8.3.

Once the medical records are obtained, they may be abstracted onto these forms by trained staff who are certified by nuMoM2b-HHS to abstract the data.

14.6 Training and Certification for Subsequent Pregnancy Chart Abstraction

14.6.1 Training Materials

A number of materials have been developed or gathered at the sites to help train the staff members who are responsible for chart abstraction of subsequent pregnancies having certain self-reported characteristics. Materials developed centrally and used across all sites include the nuMoM2b-HHS protocol and manual of operations; chart abstraction forms (listed above); model consent forms; medical record release forms, and training slides, videos, or webinars (where appropriate).

For nuMoM2b, each site developed three sets of “model” medical records and chart abstraction forms that were used to certify all other staff at the site and created a local “Rules for Chart Abstraction” document specifying how to locate information for each item on the form within the local medical records system and any other relevant information needed to supplement information in the Manual of Operations. For example, this information might include requirements for accessing records at local facilities, including staff certification and any requirements for medical release forms, and information related to chart access and organization at various facilities. The process to be used for nuMoM2b-HHS is described below.

14.6.2 Training

Training for chart abstraction consists of a variety of activities designed to ensure that staff members across all sites are able to complete the chart abstraction forms correctly and consistently. Generally, staff being trained are first given a copy of the following training materials:

- this chapter of the nuMoM2b-HHS manual of operations
- the current version of the nuMoM2b-HHS chart abstraction forms
- any locally developed “Rules for Chart Abstraction” (developed by the lead coordinator at each site as part of the training process).

Additional training materials may be provided or a Webinar may be conducted to address questions as training needs are identified.

Each staff member is expected to become familiar with: the organization of and information in the manual of operations and chart abstraction forms; the requirements for accessing medical records at facilities where the participant receives care during pregnancy through 14 days postpartum; the organization of the medical records at facilities where the participants are likely to receive care; and the activities surrounding chart abstraction.

For the nuMoM2b-HHS, a complete set of records for two nuMoM2b pregnancies during which the participant had a hypertensive disorder of pregnancy will be used for certification. If possible, one of these participants should also have had diabetes (either gestational or Type I or Type II). If such cases were used for nuMoM2b certification, these can be used. If not, it may be necessary to gather a complete set of medical records for an additional nuMoM2b participant. Once all records are gathered for the two cases, the lead coordinator will maintain a complete set of records for each case and also create a subset of the records limited to those that are most likely to be available for many nuMoM2b-HHS participants with signed medical records release forms for abstraction of subsequent pregnancies. This limited set will consist of the discharge summary from the delivery hospitalization, labor and delivery notes, and vital signs and laboratory results from the delivery hospitalization. The lead coordinator then abstracts the records for these two cases on the chart abstraction forms for the nuMoM2b-HHS first using the limited set of records, then reabstracting the data on a second set of forms using all available medical records. Any differences in results using the limited versus complete set of records should be noted in a separate document. The PI or lead investigator at a subsite reviews the abstracted nuMoM2b-HHS forms using both record sets and adjudicates the responses with the lead coordinator as needed. These forms become the “answer keys” that are used to train and certify other staff at the site for nuMoM2b-HHS chart abstraction of subsequent pregnancies.

The lead coordinator at each site or subsite trains all other staff at the site or subsite in chart abstraction for the nuMoM2b-HHS. After the initial review of available materials and instructions as noted above and prior to completing any forms, the trainees meet with the lead coordinator, who is familiar with the nuMoM2b-HHS cross-site and local requirements for chart abstraction. He or she reviews a number of topics with the trainees including:

- motivation for and goals of chart abstraction;
- overview of the nuMoM2b-HHS subsequent pregnancy chart abstraction forms;
- access, storage and security of medical records for the study;
- review of the general guidelines for abstracting data and completing the subsequent pregnancy chart abstraction forms (and how they differ from nuMoM2b if the trainee abstracted data for that study);
- review of site specific information regarding the organization of medical records and the likely location of various types of information;
- discussion of common problems; and
- discussion of trainee questions regarding the materials and any PowerPoint, webinar, or other instructional program available for training.

After this overview, trainees receive the limited set of records for one of the training cases with a set of blank nuMoM2b-HHS chart abstraction forms. They are asked to review the records and complete the chart abstraction forms using the information available in the medical records that they receive. They should refer to the manual as needed when completing the forms, and maintain a list of questions that they have during this exercise. They should then complete a second set of forms using all of the available records for the same case. The lead coordinator then compares the forms completed by the trainee against the “answer keys” created above for nuMoM2b-HHS, noting any discrepancies. He or she then discusses any discrepancies with the trainee, adjudicating differences and providing additional training as required. If a trainee was certified for chart abstraction for nuMoM2b, they are then considered trained for nuMoM2b-HHS.

If the trainee was not certified for chart abstraction during nuMoM2b, the trainee abstracts data for the other participant case with a hypertensive disorder identified for use during nuMoM2b-HHS certification. Again, the trainee abstracts the data using the abbreviated set of records and the complete set of records. The lead coordinator compares the trainee’s responses to the “answer keys” for the case. Any discrepancies are discussed and retraining is provided as needed. If the coordinator is not satisfied with the production of the trainee, discrepancies are discussed with the trainee and additional training is conducted as deemed necessary by the coordinator. If the lead coordinator is not comfortable certifying the trainee at that point, the PI is consulted and a decision is made to develop an answer key for another case, conduct additional remedial training and ask the trainee to abstract data for a third record, or the lead coordinator and PI decide to train a different staff member for chart abstraction. If an additional case is selected, the coordinator and PI review the abstraction of this case and jointly decide whether to certify the staff member in the area of chart abstraction. If abstraction of this record is not satisfactory, the trainee fails certification and another staff member should be selected to be certified for this activity.

14.6.3 Certification

The PI or lead investigator for each site do not require certification. Staff certified for chart abstraction during nuMoM2b are considered certified after they review this chapter of the nuMoM2b-HHS manual of operations and the nuMoM2b-HHS chart abstraction forms, attend a brief training session at a Steering Committee meeting or with a certified staff member, abstract data on the nuMoM2b-HHS chart abstraction forms using both the limited and complete records for one certification cases with a hypertensive disorder of pregnancy, and discuss the results with the PI or a lead coordinator. The lead coordinator should notify RTI of the name and staff ID number of all staff meeting certification in this manner.

All individuals not certified for chart abstraction during nuMoM2b, must follow all of the training procedures outlined above. The lead coordinator’s completion of the nuMoM2b-HHS chart abstraction forms using both the limited and complete set of records for the two cases identified above and subsequent discussion with the site PI to adjudicate any potential discrepancies certifies her or him to abstract data for nuMoM2b-HHS. The site PI (lead subsite investigator) informs the DCAC of the completion of this process, identifying the lead coordinator being certified, her/his nuMoM2b-HHS staff ID, and the date certified. An individual must be certified by the site PI or lead investigator before certifying other staff.
Other coordinators or research assistants must be certified by a site PI, lead investigator, or lead coordinator before she or he can train and certify other chart abstraction staff. For additional individuals trained to abstract chart abstraction data at each site or subsite, the lead coordinator reviews all chart abstraction forms for certification cases and discusses any discrepancies as above. If the quality of the work of the trainee is uneven, the coordinator discusses the performance of the trainee with the local PI. If they agree that the quality is sufficient to certify the trainee in chart abstraction, the lead coordinator sends an e-mail to the DCAC documenting the certification process and listing the name and nuMoM2b staff ID number of the individual being certified.

Once documentation of certification is received at the DCAC, certified staff may begin completing chart abstraction forms for nuMoM2b-HHS participants.

### 14.7 General Rules for Abstraction

#### 14.7.1 Overview and General Instructions

Before beginning to abstract data, study the abstraction forms to learn the intent of the items and become familiar with the arrangement of items on the forms. The goal is to collect accurate information by using the abstraction form according to sound data collection practices. To reach this goal, learn the content of the abstraction forms and the following guidelines for using them:

- Obtain as many of the medical records from conception through 14 days postpartum as possible for each pregnancy for which a participant self-reports an APO during an interval contact given documented authorization of access to these medical records;

- Confirm that the medical records belong to the correct subject and are related to the identified subsequent pregnancy by comparing the participant’s name and identifying information to information on the contact form or in WebCATI and the date of delivery to the date from the Interval Contact Form identifying the pregnancy to be abstracted. This is important because many women may have similar names and record numbers.

- Always review the requested medical records thoroughly before completing the abstraction. Skim all documents/pages in the specified records to locate necessary information.

- Complete as much as possible of each section for the participant before going on to a new section, but return to a section if additional information is found at a later time.

- Do not interpret data. Abstract information exactly as it is given in the records.

- Never guess an answer. If an answer is not apparent, consult the specifications in this manual for clarification. If the correct answer is still uncertain, ask the local PI or co-PI to adjudicate the information. If questions remain or if the issue may be common across sites, raise the issue with the DCAC or on a coordinators call so that a common solution can be reached.

- All dates require a 2-digit month, 2-digit day and 4-digit year. If the month, day or year is unknown, enter -8 in the field that is not documented in the chart. For example, if the woman was born in June 1975 and the day of birth is not recorded in her chart, enter 0 6 / - 8 / 1 9 7 5 in the date field. If the month, day and year are all unknown enter -8 / _ _ / _ _ _ _ in the month field.
Whenever possible, record the units or measurements as provided in the chart (i.e., do not round or convert). For some questions, the data collection forms give multiple coding fields for different units of measurement. In these cases, fill in only one of the coding fields, and do not fill in all options. For example, the baby’s birth weight may be recorded in either grams or pounds and ounces but not both. If the chart includes the metric units, record these rather than the English units. Record the English units in the appropriate space only if these units are used in the chart.

Expected ranges are provided for questions, as applicable. The ranges are possible values for the questions (e.g., a possible range for gestational age of live born babies is 20-45 weeks). Occasionally a legitimate answer is less than or more than the specified range. When this occurs, the data management system may prompt the user to confirm that the value has been checked and that it is correct.

When completing the forms hard copy, data should be recorded clearly and legibly in blue or black ink.

If data are changed on a hard copy form, cross out the initial answer and write the corrected answer above or to the side of the original answer. Initial and date all changes in the margin of the form.

After all entries for a given form have been completed, every question that should not have been skipped should have an answer.

14.7.2 Form Headers
Section 7.4.4 of the nuMoM2b HHS Manual of Operations describes how to complete the form headers. For chart abstraction forms, the Staff ID should be the ID of the staff member who finalizes the form and ensures that all available data are recorded correctly. The date abstracted should be the date that a staff member finalizes the form and ensures that all data are available before beginning to enter data into the data entry system.

The Study ID and “Date This Pregnancy Ended” need to be on each physical page of each form, but not front and back if double sided. The Staff ID and Date Form Completed need to be written only on the first page of each paper form. In general, the “Date this Pregnancy Ended” is the date on which the last fetus is delivered or expelled from the womb.

If the header includes a space for “Fetus/Baby Number,” enter the fetus number (01-08) corresponding to the baby/fetus to whom the form applies from the first column of the table on Form P5A, Section B, Question 4.

14.7.3 General Missing Data Codes for Chart Abstraction
A “-8” is used to indicate that an answer is missing, unknown, not recorded or not done.

14.7.4 Hierarchy of Elements when Information Conflicts
When completing the chart abstraction data collection instruments, the abstractor may find discrepancies for a given question in the chart. For example, the chart may include:

- different modes for the same delivery
When attempting to reconcile these types of discrepancies in the chart, first check with the delivery hospital to see if they have the correct information and, if needed, a local investigator to see if he or she can help interpret information in the chart. If not, seek guidance from the DCAC, as these problems may be common across sites and should be addressed in a uniform manner. The DCAC will work with the study investigators and site coordinators to build a set of guidelines for specific situations.

14.7.5 No Charting by Exception

If an answer for an item on a form is not found in a chart, do not assume that the answer is negative. Review the available portions of the record looking for a response to the item requested on the form. Even if a condition is not marked on a list where expected, it may be mentioned in provider notes. If no answer to the question is recorded in the portions of the chart(s) that are acquired, use the “Not recorded” or “Unknown” option if this is available or record ‘-8’ in the first set of boxes for an answer. Any exceptions to this rule are noted on the instructions below for that particular item.

14.7.6 Checking Entries on a Form

When all available data have been entered into the chart abstraction form and while the records are still readily available, verify that the abstracted data are complete and correct. The data verification system reviews the form for major inconsistencies and missing data and reports problems for the abstractor to review before marking the form as complete. It is important to run this report and review the form as soon as the records are entered, while the contents and order of data in the chart are familiar to the abstractor. Even if all appropriate questions are answered, the effort is in vain if the data entered into the computer are inaccurate or incomplete.

Some of the purposes of checking are:

- To catch and correct, or explain, errors and omissions in recording. Common errors that can be caught while checking include omitted codes and errors in entering codes. Return to the medical records to retrieve any data that were overlooked.

- To learn from mistakes so they are not repeated. Study the item specifications before abstracting data for the first participant and refer to them while checking data. Notice the kinds of mistakes recorded in order to avoid making the same mistakes again.

- To clarify handwriting on paper forms and write out abbreviations on paper forms or in the computer. Go over the responses; rewrite if necessary. Write out all but the most common abbreviations.

- To add any additional comments that might help explain a response.

When recording information, remember that, regardless of how carefully the medical records were researched for needed data, all efforts are wasted if the answer is not recorded properly and legibly.
14.8 Form P5A: Subsequent Pregnancy Outcome Summary

14.8.1 General Instructions
Completion of this form is triggered by the answers to a series of questions on Form TXX (i.e., T01, T02, T03, etc.) related to each completed delivery during an interval contact. These questions provide 1) the participant’s self-report of any of the following for that pregnancy: live birth less than 370 weeks EGA, stillbirth, a pregnancy loss less than 200 weeks EGA, hypertensive disorder, gestational diabetes, singleton baby weighing less than 2500 grams (5 lbs., 6 oz.) at birth, or multiple gestation, and 2) the participant’s agreement to let the site request access to medical records for the pregnancy. A participant may identify and agree to let the site seek medical records for more than one subsequent pregnancy that meets the conditions for being abstracted during a given interval contact or across interval contacts.

Study IDs of participants reporting one or more of the above conditions for a given pregnancy are listed on a report provided by the Data Coordinating and Analysis Center (DCAC). Prior to beginning to abstract records for a listed pregnancy, briefly review Section E or E2 of the TXX reporting the end of the identified pregnancy(ies) to ascertain the conditions reported by the participant so that you are aware of their responses as the case is abstracted.

Form P5A should be completed for every subsequent pregnancy to be abstracted for which medical records are retrieved. If you are unable to get the medical records for one of the subsequent pregnancies for which the participant agreed to abstraction during an interval contact (e.g., corresponding medical records release form was not signed, records could not be retrieved), note this on Form HXX, Accounting for Missing and Mistimed Data, and Form P5A does not need to be completed for that pregnancy.

14.8.2 Question-by-Question Specifications
At the top of the first page of the form, enter the participant’s Study ID, the Date This Pregnancy Ended (the date of the delivery or expulsion of the last fetus or baby associated with the subsequent pregnancy being abstracted) in the format mm/dd/yyyy, the ID of the staff member finalizing and verifying completion of the form, and the date the form was completed (mm/dd/yyyy). If the form is printed front and back, you do not need to write this information on the back of the form. If forms are printed one-sided, write the Participant’s Study ID and the Date This Pregnancy Ended on the second page of the form as well.

Section A. Medical Records Available for Review
Sites are asked to acquire as many of the medical records as possible associated with the pregnancy from conception through 14 days postpartum. However, we realize that not all of these records will be available for this retrospective review of pregnancy outcomes and that participants may have begun care a different points during their pregnancies. Therefore, this section documents which records were available for review at the time that the nuMoM2b-HHS chart abstraction forms for this pregnancy were completed.

The first question records which of the medical records from the birth hospitalization or time of the abortion are available. A check next to a record type indicates that records of that type were available.
P5AA01a  Labor and delivery notes

Check the box next to “Labor and delivery notes” if any care provider notes were available from the delivery hospitalization. Do not check the box if these records were not available. Code “01” if checked, blank otherwise.

P5AA01b  Discharge summary

Check the box next to “Discharge summary” if the discharge summary was available from the delivery hospitalization or after a medical procedure related to the time of the abortion. Do not check the box if these records were not available. Code “02” if checked, blank otherwise.

P5AA01c  Vital signs

Check the box next to “Vital signs” if any information on vital signs (at least blood pressures) is available from the delivery hospitalization or time of the abortion. Do not check the box if these records were not available. Code “03” if checked, blank otherwise.

P5AA01d  Laboratory results

Check the box next to “Laboratory results” if any laboratory results are available from the delivery hospitalization or time of the abortion. Do not check the box if these records were not available. Code “04” if checked, blank otherwise.

P5AA01e  Other records

Check the box next to “Other records” if other records were available from the delivery hospitalization or time of the abortion. In particular, records of interest might be from a clinic visit at the time an early pregnancy loss was diagnosed. Do not check the box if no records from near the end of the pregnancy other than those documented above were available. Code “05” if checked, blank otherwise.

The second question records which medical records from conception through 14 days postpartum that are not associated with the end of the pregnancy are available. A check next to a record type indicates that records of that type were available.

P5AA02a  Rehospitalization records within 14 days of delivery

Check the “Yes” box next to “Rehospitalization records within 14 days of delivery” if any records from one or more rehospitalizations within 14 days of delivery are available. In particular, we are interested in discharge summaries, care provider notes, vital signs (especially blood pressures) and laboratory results from these rehospitalizations. However, access to all of these types of records is not required to check the box, just some of them. Check the “No/NA” box if no records from rehospitalizations within 14 days postpartum are available. Answer choices: Yes (01); No/NA (02).
P5AA02b  Antenatal hospitalization records

Check the “Yes” box next to “Antenatal hospitalization records” if any records from any antenatal hospitalization are available. In particular, we are interested in discharge summaries, care provider notes, vital signs (especially blood pressures) and laboratory results from antenatal hospitalizations. However, access to all of these types of records is not required to check the box, just some of them from at least one hospitalization. Check the “No/NA” box if no records from antenatal hospitalizations are available. Answer choices: Yes (01); No/NA (02).

P5AA02c  Prenatal records

Check the “Yes” box next to “Prenatal records” if any prenatal records from clinic visits are available. In particular, we are interested in visit summaries, care provider notes, vital signs (especially blood pressures) and laboratory results from prenatal care visits. However, access to all of these types of records from throughout the pregnancy is not required to check the box, just some of them from sometime before the delivery hospitalization or abortion. Check the “No/NA” box if no prenatal records are available. Answer choices: Yes (01); No/NA (02).

Section B.  Pregnancy Outcome Summary

P5AB01  Hypertension, proteinuria, or related condition at any time during pregnancy

Mark “Yes” if, while perusing the available medical records, the abstractor notes that the participant was diagnosed with any hypertensive, proteinuric, or related condition or notes any evidence that the participant might meet any of the definitions for any of the hypertension-related diagnoses outlined in Section 14.2.5 of this chapter at any time prior to or during pregnancy through 14 days postpartum. This includes hypertension and/or proteinuria prior to pregnancy or during pregnancy before 20 weeks of gestation, even if there is no evidence of new onset maternal hypertensive/proteinuric disorders at or after 20 weeks of gestation. Mark “No / not documented” otherwise. If “Yes” is checked and the pregnancy lasted at least 20 weeks (i.e., outcome for at least one fetus was a live birth or a stillbirth), complete the Form P5C, Subsequent Pregnancy – Maternal Hypertensive Disorders, for the pregnancy being abstracted. Answer choices: Yes (01), No / not documented (02).

P5AB02  Gestational diabetes during this pregnancy

Peruse the available records from the delivery hospitalization, and mark “Yes” if the record mentions gestational diabetes (diabetes that developed during the course of this pregnancy, gestational diabetes mellitus, GDM). Gestational diabetes may be documented clinically or in any of the manners specified in Section 14.2.7 above. If the participant has had diabetes at any time before this pregnancy that was outside of a previous pregnancy or if there is no mention of diabetes in the record, mark “No / not documented.” Answer choices: Yes (01), No / not documented (02).
Number of fetuses this pregnancy

Enter the total number of fetuses this pregnancy as listed in the available records. That is, enter 01 for singleton, 02 for twins, 03 for triplets, etc. Count all fetuses, including those that are known to have resorbed or died in utero prior to delivery. Enter a two digit number. If the total number of fetuses is unknown, enter -8. Expected range: 01 through 08, -8.

One row of table 4 is completed for each fetus reported in question P5AB03, including any documented “vanishing twins.” When possible, list fetuses in the table in the order of birth or outcome ascertainment. Instructions for the variables pertain to each row of the table in question 4, although they are given only once. The “?” in the variable name would be replaced by “a” through “h” to indicate the row.

Fetus Number (Column 1)

This answer is a constant for each row of the table and does not need to be entered into the keying program. The fetus number is 01 for row a, 02 for row b, 03 for row c, 04 for row d, 05 for row e, 06 for row f, 07 for row g, and 08 for row h.

Date of Outcome (Column 2)

This is the date that the pregnancy ended for this fetus, whether it ended by in utero death, delivery (vaginal or cesarean), surgery, or termination. It may be a date early in the pregnancy if the fetus is resorbed or spontaneously aborted, the date that a fetus was known to have died in utero (whether aborted or stillborn), the date of a spontaneous abortion or elective termination, or the delivery date of a live born or stillborn baby. Record the earliest known complete date for any of those events for this fetus (e.g., if a fetal death is diagnosed on a specific date earlier than the date of abortion or delivery, use the date that the fetal death was diagnosed; if the date of fetal death is not known, use the date the fetus was aborted or delivered). In cases of fetal reduction, the date of the fetal reduction should be entered for appropriate fetuses rather than the date of delivery of the remaining fetus(es). Note that it is possible for multiple births to end on different days. If no specific date is known for the date of outcome for a fetus, enter -8 for the missing portion(s) of the date. (Ranges: month (P5AB04?2_M) -8, 1-12; day (P5AB04?2_D) -8, 1-31; year (P5AB04?2_Y) -8, 2010-2017).

Best obstetric estimate of gestational age (Column 3)

Record the best obstetric estimate of gestational age. Calculate the gestational age using the estimated due date given in clinical records and the date of outcome for this fetus from the corresponding row of Column 2. The Gestational Age Calculator on the nuMoM2b website can be used for this purpose. If one of the above dates is missing, use the clinical estimate of gestational age provided in the medical records. The estimate should be entered as weeks, P5AB04?3_W (Range: 0-42, -8), and days, P5AB04?3_D (Range: 0-6). Enter -8 for weeks if the estimated gestational age is unknown.

Outcome (Column 4, specific to fetus)

Record the outcome of the pregnancy for this fetus. Note that the outcome may differ by fetus for multiple gestations. Answer choices with relevant definitions are:
LB=live birth (01): an infant of at least 20^0 weeks gestational age that demonstrates signs of life by direct observation after birth (movement, 1 or 5 minute Apgar scores >0), regardless of attempts at resuscitation and subsequent Apgar scores.

SB=Stillbirth (02): a fetal death at a project EGA of 20^0 weeks or greater with Apgar scores of 0 at 1, 5, and 10 minutes with no other signs of life by direct observation.

SA=spontaneous abortion (03): fetal death leading to vaginal delivery or dilatation and curettage/evacuation, or spontaneous expulsion of a liveborn fetus due to any cause before 20^0 weeks estimated gestational age. Additionally, any abortion not meeting the criteria for “elective termination” or “indicated termination” delineated below will be considered a spontaneous abortion. A documented vanishing twin would also fit this category.

ET=elective termination (04): Termination is an induced delivery or dilatation and curettage/evacuation of a fetus before 20^0 weeks estimated gestational age in the absence of a diagnosis of preterm contractions or labor, PROM, membrane prolapse, or fetal death. A termination is elective if performed at the mother’s request for reasons other than maternal health or fetal disease.

IT=indicated termination (05): Termination is an induced delivery or dilatation and curettage/evacuation of a fetus before 20^0 weeks estimated gestational age in the absence of a diagnosis of preterm contractions or labor, PROM, membrane prolapse, or fetal death. A termination is indicated if it is performed for reasons of maternal health or fetal disease.

DK=unknown (-8): outcome for this fetus is unknown.

P5AB04?5 Sex (Column 5, gender specific to the fetus)
Mark the answer to indicate the fetus/infant gender designated in the delivery note. In general, gender of the fetus/baby is specified in the note as “Male” (01) or “Female” (02).
Gender is designated as “Ambiguous” (03) when gender is evaluated but cannot be determined.
Gender is designated as “Unknown” (-8) when gender is not recorded at delivery.

P5AB04?6a If the birthweight is documented in grams in the delivery note of the medical record, enter the first recorded birth weight in grams and do not complete question P5AB04?6b. (Range: 180-5999 grams). If the birth weight is recorded in pounds and ounces, leave this answer blank and answer P5AB04?6b instead. Do not convert from pounds and ounces to grams. If the birth weight of this fetus/baby is not recorded in the medical records at all, enter -8 for grams and do not complete question P5AB04?6b.

P5AB04?6b Answer this question only if birth weight is not recorded in grams in the delivery notes, but is recorded in pounds and ounces.
Enter the first recorded birth weight in pounds and ounces, as documented in the delivery notes (Range: 0 to 13 pounds; 0 to 15 ounces).
14.8.3 Next Step: Identify Additional Chart Abstraction Forms to Complete

After completing Form P5A, review the answers to the forms. Use the following criteria to identify additional forms that the site should complete:

<table>
<thead>
<tr>
<th>Form</th>
<th>Criteria for Completion</th>
</tr>
</thead>
</table>
| P5B: Subsequent Pregnancy – Labor, Delivery, and Postpartum | Complete if the pregnancy ended at 20 weeks or more AND at least one fetal outcome was LB (01) or SB (02) in Column 4 of the table in Section B, question 4 AND at least one of the following is true:  
  - The best estimate of gestational age (column 3) of a live born baby (column 4 is LB [01]) is less than (<) 37 weeks and 0 days.  
  - Any fetus was stillborn (any Column 4 outcome is SB [02])  
  - The pregnancy was complicated by a hypertensive disorder (the answer to P5AB01 is Yes [01])  
  - The pregnancy was complicated by gestational diabetes (the answer to P5AB02 is Yes [01])  
  - A singleton baby weighed less than 2500 grams or 5 pounds, 6 ounces at birth [P5AB03=01 AND P5AB04a4 (Outcome) is LB (01) AND the birth weight listed in the first row of column 6 is less than 2500 grams if given in grams OR less than 5 pounds and 6 ounces if recorded in pounds and ounces]  
  - The pregnancy was multiple gestation [the answer to P5AB03 is more than (>) 01]. |
| P5C: Subsequent Pregnancy – Maternal Hypertensive Disorders | Complete if at least one fetal outcome was LB (01) or SB (02) in Section B, Question 4, Column 4 of the table AND the pregnancy was complicated by a hypertensive disorder [the answer to P5AB01 is Yes (01)]: |
| P5D: Subsequent Pregnancy – Loss <20 Weeks EGA | Complete form P5D for each fetal loss before 20 weeks best obstetric estimate of gestational age identified in the table in Section B, Question 4. That is, complete one form P5D for each fetus (line in the table) with an EGA listed as less than 20 weeks AND an outcome (column 4) of SA (03), ET (04), OR IT (05). |
| P5E: Subsequent Pregnancy – Stillborn Workup | Complete form P5D for each stillborn baby identified in the table in Section B, Question 4. That is, complete one form P5E for each fetus (line in the table) with an outcome (column 4) of SB (02). |
| P5F – Subsequent Pregnancy – Record of Adjudication for Maternal Hypertensive Disorder | Completion of this form cannot be determined based on answers provided on this form (P5A). Form P5F is triggered by the answer on Form P5C, Section E, Question 1 as discussed in the question-by-question specifications for Form P5C. |

If none of the above criteria for completing additional forms are met, chart abstraction is complete.

14.9 Form P5B: Subsequent Labor, Delivery, and Postpartum

14.9.1 General Instructions

Complete form P5B once for each subsequent pregnancy reported on form P5A where the participant delivered at least one fetus at greater than or equal to 20 weeks EGA and had one or more of the following documented on Form P5A: live birth less than 37 weeks EGA, stillbirth, singleton baby weighing less than 2500 grams (5 lbs, 6 oz) at birth, or multiple gestation, or the
pregnancy was complicated by hypertension (including chronic hypertension), preeclampsia, proteinuria (including prepregnancy or before 20th weeks EGA), or gestational diabetes (see Section 14.8.3). This form records the provider's primary indication for delivery, all conditions known to be present during labor and delivery, information related to the occurrence of preterm birth and diabetes, the participant’s prepregnancy and delivery body weights, and fetal biometry by ultrasound after 20 weeks EGA.

14.9.2 Question-by-Question Specifications

At the top of the form, enter the participant’s Study ID, the date that the pregnancy being abstracted ended (date of the last outcome in case of outcomes on different days, see column 2 of the table in Section B, question 4 of P5A), the ID of the person finalizing and verifying completion of the form, and the date the form was completed in mm/dd/yyyy. The participant’s Study ID should be written on the front of every physical page of the form. The Staff ID and date only need to be recorded on the first page of the form.

Section A. Indication for Delivery

Section A, question 1: PRIMARY reason for delivery

The question on the first page of the form collects the one primary reason that the participant’s medical record indicated as reason for delivery. Provide only one answer to this question. This is the reason indicated by the provider or the medical record, and it does not need to meet any specific diagnostic criteria. The descriptors for this section are provided to facilitate your review of the delivery notes, and provide alternate words that might be used to describe a diagnosis. These descriptors are not meant to serve as definitions. Ask the local PI or co-PI to review the medical record if you are unable to determine the single primary reason leading to delivery.

P5BA01a Labor

Check the box for this answer if the medical record indicated that the primary reason the participant was delivered was labor. This may be indicated as “early” or “active” labor depending on the cervical dilatation. This may also apply if “imminent delivery” is anticipated to occur.

P5BA01b Rupture of membranes

Check the box for this answer if the medical record indicated that the primary reason the participant was delivered was “Rupture of membranes.” This may be indicated as “ROM,” (rupture of membranes), “SROM” (spontaneous rupture of membranes), “PROM,” (premature rupture of membranes), or “pPROM,” (preterm premature rupture of membranes) depending on the gestational age at which this event occurred.

P5BA01c Post due date

Check the box for this answer if the medical record indicated that the primary reason the participant was delivered was that the pregnancy had extended beyond its due date (i.e., a pregnancy that reached or exceeded 40th weeks EGA).

P5BA01d Placenta previa

Check the box for this answer if the medical record indicated that the primary reason the participant was delivered was “Placenta previa,” a condition where
the all or part of the placenta covers the cervix. The terms “complete,” “partial” or “marginal” placenta previa may apply here.

P5BA01e  **Abruptio placenta**

Check the box for this answer if the medical record indicated that the primary reason the participant was delivered was confirmed or suspected “Abruptio placenta,” which may be described as “abruption” (acute or chronic) or “premature separation of the placenta.”

P5BA01f  **Intrauterine fetal growth restriction (IUGR or SGA)**

The box next to “Intrauterine fetal growth restriction” should be checked if the medical record indicated that the primary reason the participant was delivered was that the fetus is deemed to be “small for gestational age.” This is commonly abbreviated “IUGR,” or “SGA.” Occasionally an estimated fetal weight (EFW) may be described as being less than the 10th percentile for gestational age, which is another synonym for IUGR.

P5BA01g  **Intrauterine fetal demise (IUFD)**

Check the box next to “Intrauterine fetal demise” if the medical record indicated that the primary reason the participant was delivered was that the fetus died in utero. This may be abbreviated “IUFD,” which could stand for either “intrauterine fetal demise” or “intrauterine fetal death.” Usually there will be notations that fetal cardiac motion (“FCM” or “CM”) is absent when an IUFD occurs.

P5BA01h  **Oligohydramnios / anhydramnios**

Check the box next to “Oligohydramnios / anhydramnios,” if the medical record indicated that low or no amniotic fluid is the primary reason the participant was delivered. This may be noted as an amniotic fluid index of <X cm or maximum vertical amniotic fluid pocket <Y cm.

P5BA01i  **Polyhydramnios**

Check the box next to “Polyhydramnios,” if the medical record indicated that elevated amniotic fluid is the primary reason the participant was delivered. This may be noted as an amniotic fluid index of >X cm or maximum vertical amniotic fluid pocket >Y cm.

P5BA01j  **Intraamniotic infection/chorioamnionitis**

Check the box next to “Intraamniotic infection/chorioamnionitis” if the medical record indicated that confirmed or suspected evidence of infection of the amniotic fluid and surrounding membranes is the primary reason the participant was delivered. This may be denoted intrauterine infection, “IUI,” “chorio,” or “amnionitis,” all terms that are synonymous for this diagnosis.

P5BA01k  **Abnormal fetal testing**

Fetal testing includes a variety of different options to evaluate the fetal condition, such as, use of non-stress testing (NST), contraction stress testing (CST), biophysical profile (BPP) and application of Doppler velocimetry. Check the box next to this item if the medical record indicated that abnormal results for any of these tests were the primary reason for delivery. If this item
If the primary reason for delivery is abnormal fetal testing, specify the reason for fetal testing and check all fetal testing abnormality(ies):

P5BA01k1 Primary indication for fetal testing

Specify the primary indication for fetal testing as open text.

P5BA01k2a Non-reactive NST

Select “Non-reactive NST” if the medical record indicated that the fetal heart rate monitoring is found to be non-reactive. “NR NST” is a common abbreviation for this.

P5BA01k2b Positive CST

Select “Positive CST” if the medical record indicated that the fetal heart rate monitoring is found to be positive. “+ CST” is a common abbreviation for this.

P5BA01k2c Abnormal biophysical profile (BPP)

Select “Abnormal biophysical profile (BPP)” if the medical record indicated that the result of this test is <6. This test has five components: a non-stress test, evaluation of amniotic fluid volume, and ultrasound assessment of fetal movement, breathing and tone. When each of these components is normal or present, a score of 2 is applied. The maximum score is 10, which is considered normal or reassuring. A score of 8 (2 points off for any reason) is also considered normal or reassuring. An abnormal score is 6 or less; points may be subtracted for any reason.

P5BA01k2d Abnormal fetal heart rate tracing

This option should be selected if the medical record indicated that, for any reason, the fetal heart rate tracing is found to be abnormal. The more specific non-reactive NST and/or positive CST should apply if the patient was in antepartum testing at the time the result was obtained. This result could apply if the patient presented to the obstetrical unit for some other reason.

P5BA01k2e Abnormal Doppler studies

Abnormal Doppler studies should be selected if the medical record indicated that a Doppler velocimetry interrogation of any blood vessel was obtained for any reason and was found abnormal; this could include evaluation of the umbilical artery, middle cerebral artery or uterine artery. Commonly encountered abnormalities for the umbilical artery would be “absent end-diastolic flow” (often abbreviated “AEDF”) or “reversed end-diastolic flow” (often abbreviated “REDF”). An abnormal middle cerebral artery result could be denoted as “MCA >1.5 MoM,” standing for a result greater than 1.5 multiples of the median for gestational age. This would be anticipated in a case where fetal anemia is suspected such as with isoimmunization or fetal infection from parvovirus. An abnormal uterine artery Doppler could be indicated by an “abnormal resistance index” and/or the presence of “notching” at the beginning of diastole. The uterine arteries are most likely to be interrogated if hypertensive disorders of pregnancy are suspected.
Other, specify
Select “Other, specify” if the medical record indicated that some other form of fetal testing indicated an abnormality.

Other fetal condition
Check the box next to “Other fetal condition (fetal anomaly, fetal hydrops, fetal cardiac arrhythmia, suspected macrosomia, etc.)” if the medical record indicated that any of these is the primary reason the participant was delivered. A fetal anomaly could be used to refer to any structural abnormality of the fetus. Fetal hydrops, also known as “hydrops,” refers to the presence of abnormal fluid collections in various body compartments. Specific fluid collections could be “ascites,” fluid collection in the abdomen, “pleural effusions,” fluid collections in the chest cavity, “pericardial effusions,” fluid collections in the sac surrounding the heart, and “scalp edema,” referring to fluid collection in the skin and subcutaneous tissue. Fetal cardiac arrhythmias may be of varying types, and include “PACS,” or premature atrial contractions, “PVCs,” premature ventricular contractions, “heart block,” “supraventricular tachycardia,” or “SVT” for short, “atrial flutter,” among others. If this item is selected, specify and code the primary condition(s) leading to delivery on the following lines.

Specify the other fetal condition as open text.
Code the other condition using the codes in Coding List 1 at the back of the form.

If the medical record indicated that some combination of anomalies or other fetal conditions were the primary reason the participant was delivered, specify up to two more conditions on the two additional lines provided (P5BA01l2a, P5BA01l2b, P5BA01l3a, and P5BA01l3b) using the above instructions for the first line. If more than three anomalies were identified, enter multiple reasons on the last line and enter code “999” for other.

Maternal medical condition or other obstetric condition – specify one below if checked
Check the box next to “Maternal medical conditions(s) or other obstetric condition” if the medical record indicated that the primary reason that the participant was delivered was a confirmed or suspected maternal medical condition or any obstetric condition not listed in the first column of the page (e.g., breech presentation). Review the list of numbered items below item P5BA01m to determine if this item should be selected. If it is selected, next review the subquestions for this answer and select the one maternal medical condition or other obstetric condition that was the primary reason for delivery.

Pregnancy associated hypertensive disease
Check the box next to “Pregnancy associated hypertensive disease (specify below)” if the medical record indicates that the primary reason that the participant was delivered was any complication of pregnancy in which high blood pressure and/or proteinuria is first encountered during this pregnancy at or after 20 weeks EGA. This refers to any of a number of medical conditions in which hypertension may be present, with terms including pregnancy-associated or pregnancy-induced hypertension (PAH or PIH), gestational hypertension, preeclampsia (mild, severe, superimposed, or just
the term preeclampsia alone), HELLP or HELLP syndrome, incomplete HELLP, and eclampsia.

If P5BA01m01 is checked, then also mark any of the specific diagnoses below that apply. For pregnancy-associated or pregnancy-induced hypertension (PAH or PIH), mark “Unspecified” (P5BA01m01a09). For “preeclampsia” without any qualifier, mark “Preeclampsia, unspecified” (P5BA01m01a05).

- P5BA01m01a01 Gestational hypertension (01)
- P5BA01m01a02 Mild preeclampsia (02)
- P5BA01m01a03 Severe preeclampsia (03)
- P5BA01m01a04 Superimposed preeclampsia (04)
- P5BA01m01a05 Preeclampsia, unspecified (05)
- P5BA01m01a06 Eclampsia (06)
- P5BA01m01a07 HELLP syndrome (07)
- P5BA01m01a08 Incomplete HELLP (08)
- P5BA01m01a09 Unspecified (-8)

P5BA01m02 Chronic hypertension
Check the box next to “Chronic hypertension” if the medical record indicated that the primary reason for delivery was a diagnosis of hypertension which predated the pregnancy or was identified before 200 weeks EGA during this pregnancy.

P5BA01m03 Pregestational diabetes
Check the box next to “Pregestational diabetes” if the medical record indicated that the primary reason for delivery was a diagnosis of diabetes applied prior to this pregnancy.

P5BA01m04 Gestational diabetes
Check the box next to “Gestational diabetes” if the medical record indicated that the primary reason for delivery was a diagnosis of diabetes that was made during pregnancy following application of glucose tolerance testing. Gestational diabetes is sometimes abbreviated GDM.

P5BA01m05 Asthma
Check the box next to “Asthma” if the medical record indicated that the primary reason for delivery was a diagnosis of asthma.

P5BA01m06 Acute cholecystitis
Check the box next to “Acute cholecystitis” if the medical record indicated that the primary reason for delivery was a diagnosis of acute inflammation of the gallbladder. Synonyms could include acute gallbladder. This most often occurs when a gallstone(s) in the gallbladder (cholelithiasis) or in the common bile duct (choledocholithiasis) blocks the outflow of bile.
Acute gastroenteritis

Check the box next to “Acute gastroenteritis” if the medical record indicated that the primary reason for delivery is an acute inflammation of the gastrointestinal tract (stomach, intestines). This would commonly manifest with nausea, vomiting and/or diarrhea.

Pneumonia or other respiratory tract infection

Check the box next to “Pneumonia or other respiratory tract infection” if the medical record indicated that the primary reason for delivery was a diagnosis of a severe respiratory infection affecting the lungs leading to admission. This will not include the common cold or viral illness, but could refer to acute bronchitis.

Urinary tract infection

Check the box next to “Urinary tract infection” if the medical record indicated that the primary reason for delivery was a diagnosis of a urinary tract infection (UTI) such as acute cystitis (infection of the urinary bladder).

Pyelonephritis

Check the box next to “Pyelonephritis” if the medical record indicated that the primary reason for delivery was a diagnosis of an acute renal (kidney) infection.

Cardiac disease

Check the box next to “Cardiac disease” and specify the type if the medical record indicated that the primary reason for delivery was some sort of cardiac disease or dysfunction. Examples of this could be congenital heart lesions like bicuspid aortic valves, or acquired ones such as mitral stenosis from rheumatic heart disease. If this answer is checked, specify the type of heart disease as open text (P5BA01m11_SP).

Cholestasis

Check the box next to “Cholestasis” if the medical record indicated that the primary reason for delivery was cholestasis of pregnancy. This is a disease process that is marked by total body itching (pruritis), and is usually self-limited. It is different than cholecystitis (inflammation of the gallbladder) and cholelithiasis (gallstones).

Systemic lupus erythematosus

Check the box next to “Systemic lupus erythematosus” if the medical record indicated that the primary reason for delivery was systemic lupus erythematosus (SLE or just “lupus” for short). This requires having at least four of the clinical criteria set forth by the American Rheumatologic Association for this disease process.

Renal disease

Check the box next to “Renal disease” if the medical record indicated that the primary reason for delivery was some sort of kidney disease or dysfunction. These could be of a variety of types including glomerulonephritis and be either primary or secondary. Common secondary causes would include diabetes and lupus. Renal insufficiency and renal failure would trigger a
positive response for this variable. If this is selected, specify the type of kidney disease as open text (P5BA01m14_sp).

**P5BA01m15 Hematologic disease (not anemia)**

Check the box next to “Hematologic disease (not anemia)” if the medical record indicated that the primary reason for delivery was any sort of blood-related disorder that is not anemia related to pregnancy or iron-deficiency anemia. This could include sickle cell trait or disease, beta-thalassemia disease, or spherocytosis, among others. If this is selected, specify the type of hematologic disease as open text (P5BA01m15_sp).

**P5BA01m16 Prior uterine surgery**

Check the box next to “Prior uterine surgery” if the medical record indicated that the primary reason for delivery was some sort of prior uterine surgery that is not a dilatation and curettage. Examples could be myomectomy or uterine septum resection. A diagnostic hysteroscopy will not qualify here. If this is selected, specify the type of prior uterine surgery as open text (P5BA01m16_sp).

**P5BA01m17 Mental health disorder**

Check the box next to “Mental health disorder” if the medical record indicated that the primary reason for delivery was a diagnosis of any sort of mental health disorder. Mental health disorders include a range of diagnoses such as anxiety, panic attacks, schizophrenia, bipolar disease, depression, and post-traumatic stress disorder (PTSD), among others. If this is selected, specify the type of mental health disorder as open text (P5BA01m17_sp).

**P5BA01m18 Maternal trauma**

Check the box next to “Maternal trauma” if the medical record indicated that the primary reason for delivery was a traumatic event during pregnancy. This could include a motor vehicle accident, a fall, or being the victim of domestic violence. If this is selected, specify the type of maternal trauma as open text (P5BA01m18_sp).

**P5BA01m19 Cancer**

Check the box next to “Cancer” if the medical record indicated that the primary reason for delivery was the diagnosis of any malignancy or its complications. Note that cervical intraepithelial neoplasia or cervical dysplasia as detected from a Pap smear is not considered a malignancy. If this is selected, specify the type of cancer (malignancy) as open text (P5BA01m19_sp).

**P5BA01m20 Transplant**

Check the box next to “Transplant” if the medical record indicated that the primary reason for delivery was a solid organ (kidney, liver, lung or heart) or bone marrow transplant or a related complication. If this is selected, specify the type of transplant as open text (P5BA01m20_sp).

**P5BA01m21 Other maternal medical or obstetric condition**

Check the box next to “Other maternal medical or obstetric condition” if the medical record indicated that any maternal or obstetrical (e.g., breech
presentation) condition not listed earlier in the form was the **primary** reason for delivery. If this is selected, specify one other maternal medical or obstetric condition as open text (P5BA01m21_sp).

**P5BA01m22 Condition not documented**

Check the box next to “Condition not documented” if there is a report that the primary reason for delivery was a maternal medical or other obstetric condition, but the type of condition is not documented in admission or progress notes.

**P5BA01n Scheduled for convenience**

Check the box next to “Scheduled for convenience” if the medical record reflects that the primary reason for delivery is for convenience either on behalf of the patient or the physician.

**P5BA01o No primary reason found in chart**

Check the box next to “No reason found in chart” if the chart is available and no primary reason for delivery is indicated in the chart.

**Section A, question 2: ALL conditions known present during labor and delivery**

The question on the second page of form P5B collects all maternal and fetal conditions known to be present during the labor and delivery hospitalization or period, including the one listed in response to the prior question. For this question, check all conditions present during labor or delivery. The descriptors for this section are provided to facilitate your review of the labor and delivery notes, and provide alternate words that might be used to describe a diagnosis. These descriptors are not meant to serve as definitions. Ask the local PI or co-PI to review the medical record if you are unable to determine if the condition was mentioned in the participant’s medical record.

**P5BA02a Labor**

Check the box for this answer if the medical record indicated that the participant was ever in labor. This may be indicated as “early” or “active” labor depending on the cervical dilatation. This may also apply if “imminent delivery” is anticipated to occur.

**P5BA02b Rupture of membranes**

Check the box for this answer if the medical record indicated that the participant’s membranes ruptured spontaneously. This may be indicated as “ROM,” (rupture of membranes), “SROM” (spontaneous rupture of membranes), “PROM,” (premature rupture of membranes), or “pPROM,” (preterm premature rupture of membranes) depending on the gestational age at which this event occurred. Do not check this box if a clinician tore the membranes as part of a procedure.

**P5BA02c Post due date**

Check the box for this answer if the medical record indicated that the pregnancy had extended beyond its due date (i.e., a pregnancy that reached or exceeded 40th weeks EGA).
P5BA02d  **Placenta previa**

Check the box for this answer if the medical record indicated that the participant had “Placenta previa,” a condition where the all or part of the placenta covers the cervix. The terms “complete,” “partial” or “marginal” placenta previa may apply here.

P5BA02e  **Abruptio placenta**

Check the box for this answer if the medical record indicated that the participant had confirmed or suspected “Abruptio placenta,” which may be described as “abruption” (acute or chronic) or “premature separation of the placenta.”

P5BA02f  **Intrauterine fetal growth restriction (IUGR or SGA)**

The box next to “Intrauterine fetal growth restriction” should be checked if the medical record indicated that the fetus is deemed to be “small for gestational age.” This is commonly abbreviated “IUGR,” or “SGA.” Occasionally an estimated fetal weight (EFW) may be described as being less than the 10th percentile for gestational age, which is another synonym for IUGR.

P5BA02g  **Intrauterine fetal demise (IUFD)**

Check the box next to “Intrauterine fetal demise” if the medical record indicated that the fetus died in utero. This may be abbreviated “IUFD,” which could stand for either “intrauterine fetal demise” or “intrauterine fetal death.” Usually there will be notations that fetal cardiac motion (“FCM” or “CM”) is absent when an IUFD occurs.

P5BA02h  **Oligohydramnios / anhydramnios**

Check the box next to “Oligohydramnios / anhydramnios,” if the medical record indicated that the participant had low or no amniotic fluid. This may be noted as an amniotic fluid index of <X cm or maximum vertical amniotic fluid pocket <Y cm.

P5BA02i  **Polyhydramnios**

Check the box next to “Polyhydramnios,” if the medical record indicated that the participant had elevated amniotic fluid. This may be noted as an amniotic fluid index of >X cm or maximum vertical amniotic fluid pocket >Y cm.

P5BA02j  **Intraamniotic infection / chorioamnionitis**

Check the box next to “Intraamniotic infection/chorioamnionitis” if the medical record indicated confirmed or suspected evidence of infection of the amniotic fluid and surrounding membranes. This may be denoted intrauterine infection, “IUI,” “chorio,” or “amnionitis,” all terms that are synonymous for this diagnosis.

P5BA02k  **Abnormal fetal testing**

Fetal testing includes a variety of different options to evaluate the fetal condition, such as, use of non-stress testing (NST), contraction stress testing (CST), biophysical profile (BPP) and application of Doppler velocimetry. Check the box next to this item if the medical record indicated abnormal results for any of these tests. If this item is selected, specify the indication for
testing and the tests that were abnormal. If this item is not selected, skip to item P5BA02l.

If one of the conditions observed is abnormal fetal testing, specify the reason for fetal testing and check all fetal testing abnormality(ies):

P5BA02k1  **Primary indication for fetal testing**
Specify the primary indication for fetal testing as open text.

P5BA02k2a  **Non-reactive NST**
Select “Non-reactive NST” if the medical record indicated that the fetal heart rate monitoring is found to be non-reactive. “NR NST” is a common abbreviation for this.

P5BA02k2b  **Positive CST**
Select “Positive CST” if the medical record indicated that the fetal heart rate monitoring is found to be positive. “+ CST” is a common abbreviation for this.

P5BA02k2c  **Abnormal biophysical profile (BPP)**
Select “Abnormal biophysical profile (BPP)” if the medical record indicated that the result of this test is <6. This test has five components: a non-stress test, evaluation of amniotic fluid volume, and ultrasound assessment of fetal movement, breathing and tone. When each of these components is normal or present, a score of 2 is applied. The maximum score is 10, which is considered normal or reassuring. A score of 8 (2 points off for any reason) is also considered normal or reassuring. An abnormal score is 6 or less; points may be subtracted for any reason.

P5BA02k2d  **Abnormal fetal heart rate tracing**
This option should be checked if the medical record indicated that, for any reason, the fetal heart rate tracing is found to be abnormal. The more specific non-reactive NST and/or positive CST should apply if the patient was in antepartum testing at the time the result was obtained. This result could apply if the patient presented to the obstetrical unit for some other reason.

P5BA02k2e  **Abnormal Doppler studies**
Abnormal Doppler studies should be checked if the medical record indicated that a Doppler velocimetry interrogation of any blood vessel was obtained for any reason and was found abnormal; this could include evaluation of the umbilical artery, middle cerebral artery or uterine artery. Commonly encountered abnormalities for the umbilical artery would be “absent end-diastolic flow” (often abbreviated “AEDF”) or “reversed end-diastolic flow” (often abbreviated “REDF”). An abnormal middle cerebral artery result could be denoted as “MCA >1.5 MoM,” standing for a result greater than 1.5 multiples of the median for gestational age. This would be anticipated in a case where fetal anemia is suspected such as with isoimmunization or fetal infection from parvovirus. An abnormal uterine artery Doppler could be indicated by an “abnormal resistance index” and/or the presence of “notching” at the beginning of diastole. The uterine arteries are most likely to be interrogated if hypertensive disorders of pregnancy are suspected.
P5BA02k2f  Other, specify
Select “Other, specify” if the medical record indicated that some other form of fetal testing indicated an abnormality. If this answer is selected, specify the testing abnormality as open text in P5BA02k2f_sp.

P5BA02l  Other fetal condition
Check the box next to “Other fetal condition (fetal anomaly, fetal hydrops, fetal cardiac arrhythmia, suspected macrosomia, etc.)” if the medical record indicated that any other fetal condition. A fetal anomaly could refer to any structural abnormality of the fetus. Fetal hydrops, also known as “hydrops,” refers to the presence of abnormal fluid collections in various body compartments. Specific fluid collections could be “ascites,” fluid collection in the abdomen, “pleural effusions,” fluid collections in the chest cavity, “pericardial effusions,” fluid collections in the sac surrounding the heart, and “scalp edema,” referring to fluid collection in the skin and subcutaneous tissue. Fetal cardiac arrhythmias may be of varying types, and include “PACS,” or premature atrial contractions, “PVCs,” premature ventricular contractions, “heart block,” “supraventricular tachycardia,” or “SVT” for short, “atrial flutter,” among others. If this item is selected, specify and code the primary condition(s) leading to delivery on the following lines.

P5BA02l1a  Specify an “other fetal condition” as open text.
P5BA02l1b  Code this condition using the codes in Coding List 1 at the back of the form.
If the medical record indicated more than one anomaly or other fetal condition present, specify up to two more conditions on the two additional lines provided (P5BA02l2a, P5BA02l2b, P5BA02l3a, and P5BA02l3b) using the above instructions for the first line. If more than three anomalies were identified, enter multiple reasons on the last line and enter code “999” for other.

P5BA02m  Maternal medical condition or other obstetric condition
Check the box next to “Maternal medical conditions(s) or other obstetric condition” if the medical record indicated that, during labor and delivery, the participant had a confirmed or suspected maternal medical condition or any obstetric condition not listed in the first column of the page (e.g., breech presentation). Review the list of numbered items below item P5BA02m to determine if this item should be checked. If it is checked, next review the subquestions for this answer and check all maternal medical conditions or other obstetric conditions that were known to be present during labor and delivery.

P5BA02m01  Pregnancy associated hypertensive disease
Check the box next to “Pregnancy associated hypertensive disease (specify below)” if the medical record indicates that the participant had high blood pressure and/or proteinuria that was first encountered during this pregnancy at or after 20 weeks EGA. This refers to any of a number of medical conditions in which hypertension may be present, with terms including pregnancy-associated or pregnancy-induced hypertension (PAH or PIH), gestational hypertension, preeclampsia (mild, severe, superimposed, or just the term preeclampsia alone), HELLP or HELLP syndrome, incomplete HELLP, and eclampsia.
If P5BA02m01 is checked, then also mark any of the specific diagnoses below that apply. For pregnancy-associated or pregnancy-induced hypertension (PAH or PIH), mark “Unspecified” (P5BA02m01a09). For “preeclampsia” without any qualifier, mark “Preeclampsia, unspecified” (P5BA02m01a05).

- P5BA02m01a01 Gestational hypertension (01)
- P5BA02m01a02 Mild preeclampsia (02)
- P5BA02m01a03 Severe preeclampsia (03)
- P5BA02m01a04 Superimposed preeclampsia (04)
- P5BA02m01a05 Preeclampsia, unspecified (05)
- P5BA02m01a06 Eclampsia (06)
- P5BA02m01a07 HELLP syndrome (07)
- P5BA02m01a08 Incomplete HELLP (08)
- P5BA02m01a09 Unspecified (-8)

P5BA02m02 **Chronic hypertension**

Check the box next to “Chronic hypertension” if the medical record indicated that the participant had a diagnosis of hypertension which predated the pregnancy or was identified before 20\(^{0}\) weeks EGA during this pregnancy.

P5BA02m03 **Pregestational diabetes**

Check the box next to “Pregestational diabetes” if the medical record indicated that the participant had a diagnosis of diabetes applied prior to this pregnancy.

P5BA02m04 **Gestational diabetes**

Check the box next to “Gestational diabetes” if the participant had a diagnosis of diabetes that was made during pregnancy following application of glucose tolerance testing. Gestational diabetes is sometimes abbreviated GDM.

P5BA02m05 **Asthma**

Check the box next to “Asthma” if the medical record indicated that the participant had asthma during labor and delivery.

P5BA02m06 **Acute cholecystitis**

Check the box next to “Acute cholecystitis” if the medical record indicated that the participant had a diagnosis of acute inflammation of the gallbladder during labor and delivery. Synonyms could include acute gallbladder. This most often occurs when a gallstone(s) in the gallbladder (cholelithiasis) or in the common bile duct (choledocholithiasis) blocks the outflow of bile.

P5BA02m07 **Acute gastroenteritis**

Check the box next to “Acute gastroenteritis” if the medical record indicated that the participant had an acute inflammation of the gastrointestinal tract (stomach, intestines) during labor and delivery. This would commonly manifest with nausea, vomiting and/or diarrhea.
**P5BA02m08  Pneumonia or other respiratory tract infection**
Check the box next to “Pneumonia or other respiratory tract infection” if the medical record indicated that the participant had a diagnosis of a severe respiratory infection affecting the lungs leading to admission for labor and delivery. This will not include the common cold or viral illness, but could refer to acute bronchitis.

**P5BA02m09  Urinary tract infection**
Check the box next to “Urinary tract infection” if the medical record indicated that the participant had a diagnosis of a urinary tract infection (UTI) such as acute cystitis (infection of the urinary bladder) during labor and delivery.

**P5BA02m10  Pyelonephritis**
Check the box next to “Pyelonephritis” if the medical record indicated that the participant had a diagnosis of an acute renal (kidney) infection during labor and delivery.

**P5BA02m11  Cardiac disease**
Check the box next to “Cardiac disease” and specify the type if the medical record indicated that the participant had some sort of cardiac disease or dysfunction. Examples of this could be congenital heart lesions like bicuspid aortic valves, or acquired ones such as mitral stenosis from rheumatic heart disease. If this answer is checked, specify the type of heart disease as open text (P5BA02m11_SP).

**P5BA02m12  Cholestasis**
Check the box next to “Cholestasis” if the medical record indicated that the participant had cholestasis of pregnancy during labor and delivery. This is a disease process that is marked by total body itching (pruritis), and is usually self-limited. It is different than cholecystitis (inflammation of the gallbladder) and cholelithiasis (gallstones).

**P5BA02m13  Systemic lupus erythematosus**
Check the box next to “Systemic lupus erythematosus” if the medical record indicated that the participant has systemic lupus erythematosus (SLE or just “lupus” for short). This requires having at least four of the clinical criteria set forth by the American Rheumatologic Association for this disease process.

**P5BA02m14  Renal disease**
Check the box next to “Renal disease” if the medical record indicated that the participant suffered from some sort of kidney disease or dysfunction during labor and delivery. These could be of a variety of types including glomerulonephritis and be either primary or secondary. Common secondary causes would include diabetes and lupus. Renal insufficiency and renal failure would trigger a positive response for this variable. If this is selected, specify the type of kidney disease as open text (P5BA02m14_sp).

**P5BA02m15  Hematologic disease (not anemia)**
Check the box next to “Hematologic disease (not anemia)” if the medical record indicated that the participant had any sort of blood-related disorder that is not anemia related to pregnancy or iron-deficiency anemia during labor
and delivery. This could include sickle cell trait or disease, beta-thalassemia disease, or spherocytosis, among others. If this is selected, specify the type of hematologic disease as open text (P5BA02m15_sp).

P5BA02m16 Prior uterine surgery

Check the box next to “Prior uterine surgery” if the medical record indicated that the participant had had some sort of prior uterine surgery that is not a dilatation and curettage or dilatation and extraction. Examples could be myomectomy or uterine septum resection. A diagnostic hysteroscopy will not qualify here. If this is selected, specify the type of prior uterine surgery as open text (P5BA02m16_sp).

P5BA02m17 Mental health disorder

Check the box next to “Mental health disorder” if the medical record indicated that the participant had a diagnosis of any sort of mental health disorder at the time of labor and delivery. Mental health disorders include a range of diagnoses such as anxiety, panic attacks, schizophrenia, bipolar disease, depression, and post-traumatic stress disorder (PTSD), among others. If this is selected, specify the type of mental health disorder as open text (P5BA02m17_sp).

P5BA02m18 Maternal trauma

Check the box next to “Maternal trauma” if the medical record indicated that the participant suffered a traumatic event during this pregnancy that affected labor and delivery. This could include a motor vehicle accident, a fall, or being the victim of domestic violence. If this is selected, specify the type of maternal trauma as open text (P5BA02m18_sp).

P5BA02m19 Cancer

Check the box next to “Cancer” if the medical record indicated that the participant was diagnosed with any malignancy or its complications at the time of labor and delivery. Note that cervical intraepithelial neoplasia or cervical dysplasia as detected from a Pap smear is not considered a malignancy. If this is selected, specify the type of cancer (malignancy) as open text (P5BA02m19_sp).

P5BA02m20 Transplant

Check the box next to “Transplant” if the medical record indicated that the participant had had a solid organ (kidney, liver, lung or heart) or bone marrow transplant and/or a related complication. If this is selected, specify the type of transplant as open text (P5BA02m20_sp).

P5BA02m21 Other maternal medical or obstetric condition

Check the box next to “Other maternal medical or obstetric condition” if the medical record reported any maternal or obstetrical (e.g., breech presentation) condition not listed earlier in the form. If this is selected, specify the other maternal medical or obstetric condition(s) as open text (P5BA02m21_sp).
P5BA02m22 Condition not documented
Check the box next to “Condition not documented” if there is a report of a
maternal medical or other obstetric condition, but the type of condition is not
documented in admission or progress notes.

P5BA02n Scheduled for convenience
Check the box next to “Scheduled for convenience” if the medical record
reflects that the delivery was scheduled for convenience on behalf of either
the patient or the physician.

P5BA02o No conditions during labor and delivery documented in chart
Check the box next to “No reason found in chart” if the chart is available and
no maternal, obstetrical, or fetal conditions are documented in the labor and
delivery chart.

The following question (Section A, Question 3) collects details about preterm birth.

P5BA03 Preterm birth is defined as delivery of a live born or stillborn infant for any
cause between 20⁰ weeks and 36⁰ weeks project EGA. A birth is classified
as preterm if any fetus from that pregnancy is delivered preterm.

If this is a preterm birth, mark “Yes,” and continue to P5BA03a.

If the delivery was not a preterm birth, mark “No / not documented,” and skip
to Section B.

P5BA03a Specify if spontaneous, indicated, non-spontaneous with no indicated reason,
or unknown (for first preterm birth if multiple gestation)

Spontaneous preterm birth (01) is defined as delivery occurring subsequent
to spontaneous onset of preterm labor or preterm Premature Rupture of the
Membranes (preterm PROM) or fetal membrane prolapse, regardless of
subsequent labor augmentation or cesarean delivery. If this is a multi-fetal
pregnancy, mark “Spontaneous” if the first preterm birth meets this definition.
Note that definition of preterm labor and preterm PROM appear below, and
the definition of membrane prolapse appears in Section 14.2.4.

Indicated preterm birth (02) is defined as delivery following induction or
cesarean delivery at <37⁰ weeks gestation due to one or more conditions that
the woman’s caregiver determines to threaten the health/life of the mother or
fetus. Many of the relevant conditions are listed in Section 14.2 with the
lengthy definition of indicated preterm birth. If this is a multi-fetal pregnancy,
mark “Indicated” if the first preterm birth meets this definition and the medical
condition leading to the delivery is specified. If this choice is selected, also
specify the medical condition leading to the delivery as open text in
P5BA03a_sp.

Non-spontaneous preterm birth (03) is defined as delivery following
induction or cesarean delivery at <37⁰ weeks gestation when the care
provider does not specify any conditions that threaten the health/life of the
mother or fetus. If this is a multi-fetal pregnancy, mark “Non-spontaneous, no
recorded indication” if the first preterm birth meets this definition.

Select Don’t know (-8) if there is not enough information in the medical
record to determine which of the above categories apply to this delivery.
If “Spontaneous” is selected, continue and answer P5BA03a1 and P5BA03a2.

If any of the other answers are selected, skip to Section B.

**P5BA03a1**

For this study, **Preterm Labor** is defined as spontaneous uterine contractions (more than 6 contractions per hour documented by tocodynamometry or by maternal history), with onset before membrane rupture, and that lead to delivery.

If the participant delivers as a result of a different primary diagnosis, she may also have a secondary diagnosis of preterm labor that ultimately does or does not lead to delivery. A secondary diagnosis of preterm labor requires more than 6 contractions per hour documented by tocodynamometry or by maternal history plus;

- documented cervical change (at least 1 cm dilation or 1 cm effacement) during the current admission OR
- cervix dilated >2 cm OR cervical effacement >80% on admission for contractions.

If the medical record documents preterm labor using the above definitions or if the delivery or discharge notes indicate preterm labor, mark “Yes” (01).

Otherwise, mark “No / not documented” (02).

**P5BA03a2**

For this study, a primary diagnosis of **Premature Rupture of the Membranes (PROM)** is defined as spontaneous rupture of the membranes before the onset of contractions, regardless of subsequent labor augmentation or cesarean delivery.

Rupture of the membranes requires a documented clinical suspicion for this diagnosis based on clinical history and/or ultrasound accompanied by any one (1) of the following:

- Visible leaking of amniotic fluid from the cervix
- Presence of vaginal indigo carmine after intra-amniotic installation; or
- Any two (2) of the following:
  - Pooling of fluid in the vaginal vault.
  - Positive Nitrazine test
  - Positive Ferning of dried vaginal fluid observed microscopically
  - Positive biochemical test for PROM (e.g., Amnisure, alpha-microglobin, MSAFP, HCG, fFN).

If the medical record documents premature rupture of membranes using the above definitions or if the delivery or discharge notes indicate premature rupture of membranes (PROM or pPROM), mark “Yes.”

Otherwise, mark “No / not documented.”
Section B. General Information

P5BB01  
**Participant’s prepregnancy weight**

Enter the participant’s prepregnancy weight from the medical record. Record the participant’s prepregnancy weight in the units in which it is listed in the medical record (kilograms [P5BB01a1] to the nearest tenth or pounds [P5BB01a2]) to the nearest pound). Round pounds to the nearest whole number, rounding ½ pound or more up. *Do not convert from one measurement to the other.* Enter -8 kilograms if the prepregnancy weight is not available. (Range: -8, 32.0 to 227.0 kilograms; -8, 70 to 500 lbs)

P5BB02  
**Participant’s weight at delivery**

Enter the participant’s weight at delivery from the medical record. Record the participant’s weight in the units in which it is listed in the medical record (kilograms [P5BB02a1] to the nearest tenth or pounds [P5BB02a2]) to the nearest pound. Round pounds to the nearest whole number, rounding ½ pound or more up. *Do not convert from one measurement to the other.* Enter -8 kilograms if the participant’s weight at delivery is not available. (Range: -8, 32.0 to 227.0 kilograms; -8, 70 to 500 lbs)

Section C. Fetal Biometry

P5BC01  
**Fetal Biometry by ultrasound after 200 weeks EGA**

Mark “Yes,” if a fetal biometry by ultrasound after 200 weeks estimated gestational age (EGA) is available. Mark “No. not documented” if this was not done or if the record is not available. Answer Choices: Yes (01); No / not documented (02).

If the answer is “Yes,” continue with P5BC01a.

If the answer is “No / not documented,” skip to Section D.

P5BC01a  
**Estimated fetal weight (EFW)**

If there is one fetus, enter the estimated weight from the ultrasound in grams (Range: 10 to 5999, -8). If estimated fetal weights are available for more than one fetus, enter the smallest estimated gestational weight in grams. If no fetal estimated gestational weights are available from the ultrasound, enter -8.

P5BC01b  
**Estimated percentile of EFW for EGA on date of ultrasound**

If there is one fetus, enter the estimated EFW for EGA from the ultrasound as a percentile in P5BC01b2 (Range: 1 to 99, -8). If the medical record indicates a percentile of <X, check the box in P5BC01b1. If estimated EFW for EGA is available for more than one fetus, enter the smallest percentile for the fetuses using the instructions above. If no EFW for EGA is available from the ultrasound, enter -8 as the percentile in P5BC01b2.

P5BC01c  
**Estimated gestational age used for clinical practice on date of ultrasound**

Record the obstetric estimate of gestational age on the date of the ultrasound. Use the clinical estimate of gestational age provided in the medical records. The estimate should be entered as weeks, P5BC01c_W
Section D. Diabetes

Diabetes diagnosed
Check all of the following options that apply. If options diabetes has been diagnosed at any time, continue to P5BD02.

P5BD01a Check this option if the medical record indicates that the participant was diagnosed with diabetes outside of pregnancy (at a time when the woman was not pregnant).

P5BD01b Check this option if the medical record indicates that the participant was diagnosed with diabetes during previous pregnancies.

P5BD01c Check this option if the medical record indicates that the participant was diagnosed with diabetes during this pregnancy.

**IF THE PARTICIPANT WAS DIAGNOSED WITH DIABETES DURING THIS PREGNANCY,** record the obstetric estimate of gestational age on the date that diabetes was first diagnosed during this pregnancy. Use the clinical estimate of gestational age provided in the medical records. The estimate should be entered as weeks, P5BD01c1_W (Range: 0-42, -8), and days, P5BD01c1_D (Range: 0-6). Enter -8 for weeks if the estimated gestational age at the time diabetes was diagnosed during this pregnancy is unknown.

P5BD01d Check this option if the medical record indicates that the participant was diagnosed with diabetes, but the timing is unknown.

P5BC01e Check this option if the woman was not diagnosed with diabetes at all or if it was not documented in the available medical records.

Worst classification of diabetes

P5BC02 Complete this question if one or more of P5BC01a through P5BC01d have been checked. Indicate the worst diabetes classification. Only check the option that corresponds to the worst clinical criteria listed in the medical record. The modified Priscilla White classification will be applied when answering this question, and the clinical criteria for those classes are provided below. To apply the White classification, the provider must know when the diabetes diagnosis was made, whether insulin is required, and whether there is organ involvement. The modified White classification is as follows:

- Gestational diabetes (diagnosed during this pregnancy) not requiring insulin or oral hypoglycemic agents. (White Class A1)
- Gestational diabetes (diagnosed during this pregnancy) requiring insulin or oral hypoglycemic agents. (White Class A2)
- Diabetes that was diagnosed after age 20 and before pregnancy with a duration of less than 10 years. There is no organ involvement. (White Class B)
Diabetes that was diagnosed between the ages of 10 and 19 and before pregnancy or diagnosed 10 to 19 years ago. There is no organ involvement. (White Class C)

Diabetes that was diagnosed before the age of 10 or 20 or more years ago. There is no organ involvement. (White Class D)

Involvement of one or more organs, if this option is selected continue to P5BC02a1.

Check not available / not documented if the medical record that she was diagnosed with diabetes outside of pregnancy or during this pregnancy but no clinical criteria recorded.

White Class F, H, R, T or some combination of these: These classifications all indicate organ involvement in the progression of the diabetes. If the participant falls into this category, also indicate the type of organ involvement in the next subsection.

If the participant does not have organ involvement, continue to Section E. If the participant has organ involvement, indicate the organs involved in P5BD02a1 through P5BD02a5.

P5BD02a1 Check if diabetic nephropathy (White Class F) is present.
P5BD02a2 Check if ischemic heart disease (White Class H) is present.
P5BD02a3 Check if proliferative retinopathy (White Class R) is present.
P5BD02a4 Check if prior kidney transplant (White Class T) was performed.
P5BD02a5 Check if other organ involvement with the diabetes is present and specify the organ involved.

Section E. Postpartum Complications

P5BE01 Cardiomyopathy

Mark “Yes,” if the participant was diagnosed with cardiomyopathy after delivery through 14 days postpartum and the diagnosis was supported by one or more cardiac imaging studies (e.g., echocardiography, MRI) or cardiac catheterization. Such patients may be diagnosed with “peripartum cardiomyopathy (PPCM)” and will typically have evidence of heart failure (pulmonary edema). Mark “No. not documented” if this diagnosis was not made or if some of the records are not available. Answer Choices: Yes (01); No / not documented (02).

14.10 Form P5C: Subsequent Maternal Hypertensive Disorders
14.10.1 General Instructions

Complete the Subsequent Maternal Hypertensive Disorders Form for each pregnancy reported on Form P5A where the participant delivered one or more fetuses at greater than or equal to 20 weeks clinical estimated gestational age (EGA) (Column 3 of the table in Section B, Question 4 of Form P5A, also indicated by at least one live birth or stillbirth in Column 4 of that table) AND a hypertensive, proteinuric, or related condition was documented on the form [i.e., the answer to P5AB01 is Yes (01)]. No more than one form is completed per pregnancy.
General approach to chart abstraction for Form P5C

The approach to chart abstraction for maternal hypertensive disorders in HHS differs from that in nuMoM2b. In nuMoM2b, using Form CMD, the abstractor reviewed the chart to determine whether a new onset hypertensive disorder of pregnancy had occurred and if so what kind, using nuMom2b definitions. Diagnoses were reported separately for the first and the worst new onset hypertensive disorder. Additional data on individual diagnostic criteria were collected and used to QA the main diagnostic findings. Clinicians’ diagnoses of new onset hypertensive disorders were not recorded, unless they were given as a reason for admission to L&D or for delivery, in which case they were recorded on Form CMA.

In nuMoM2b-HHS, it will not be possible to collect the maternal hypertensive disorder outcomes to the same level of rigor as in the parent study because of the following factors that do not pertain to subsequent pregnancies:

- nuMoM2b was a prospective study, with scheduled collection of blood pressures and ultrasound measurements in each trimester
- all nuMoM2b participants were enrolled into prenatal care during the first trimester
- enrollment criteria included planned delivery at a nuMoM2b hospital
- nuMoM2b chart abstraction was funded to attempt to access prenatal records, including those from private physician offices.

Consequently, for nuMoM2b-HHS, there will be limited ability to obtain complete antenatal information for subsequent pregnancies, because:

- it may be difficult to obtain prenatal records, particularly when care is not provided by nuMoM2b-affiliated medical practices,
- prenatal care will not always have started in the first trimester, and
- prenatal records may be missing or unavailable for some or all of the prenatal period

Therefore it will not always be possible to determine the occurrence of a hypertensive disorder of pregnancy by strict nuMoM2b criteria, and in that case the clinician’s diagnosis will be used.

Form P5C is divided into 5 sections:

A. Clinician Diagnoses
   B. Conditions Documented Prior to This Pregnancy and Outside of Pregnancy or Prior to 20th Weeks Gestation in This or Any Earlier Pregnancies
   C. Conditions Associated with Hypertensive Disorders of Pregnancy
   D. Documentation of Clinical Criteria Associated with Hypertensive Disorders
   E. Need for Adjudication

Section A of Form P5C collects clinician diagnoses: chronic hypertension, chronic proteinuria, worse clinician-diagnosed new onset hypertensive disorder of pregnancy, and HELLP syndrome. Sections B-D collect information on nuMoM2b criteria related to maternal hypertensive disorders. We have streamlined certain aspects of the data collection of nuMoM2b criteria in Sections C and D:
- The time frame is from 20\(^0\) weeks’ gestation through 14 days postpartum rather than the time frame relevant to the worst nuMoM2b diagnosis. This is more straightforward in concept.

- With the exception of dipstick urine protein values, we ask for the occurrence of laboratory values above or below specific cutoffs, e.g., platelet count <100,000/mm\(^3\), rather than the maximum or minimum value. Thus, once a qualifying value is found for a given analyte, the chart need not be further searched, unless there is some question regarding whether the qualifying value may be unrelated to a new onset hypertensive disorder of pregnancy, e.g., a lowered platelet count due to an immune clotting disorder or an elevated total bilirubin due to gallbladder disease. In that case, the chart should be further searched to determine whether there is a qualifying value that could be related.

Section E contains one question, whether the data need adjudication. For details, see “Section E” in Section 14.10.2 and Section 14.14.13 (“Form P5F: Subsequent Pregnancy – Record of Adjudication for Maternal Hypertensive Disorder”).

### 14.10.2 Question-by-Question Specifications

**Note:** Before reading further, please review the definitions of the Hypertensive/Proteinuric Outcomes in Section 14.2.5 of this chapter.

At the top of the form, enter the participant’s Study ID, the date that the pregnancy being abstracted ended (format mm/dd/yyyy; in case of multiple gestation, use the latest date listed in P5A, Section B, Question 4, column 2), the ID of the person finalizing and verifying completion of the form, and the date the form was completed in mm/dd/yyyy format. The participant’s Study ID and date this pregnancy ended should be written on the front of every physical page of the form. The Staff ID and date only need to be recorded on the first page of the form.

**Section A. Clinician Diagnoses**

**Note:** The questions in this section refer to diagnoses that the clinician made in the medical record. Questions A1a and A1b pertain to diagnoses and test results at baseline, i.e., prior to this pregnancy or before 20\(^0\) weeks clinical estimated gestational age (EGA) for this pregnancy.

**P5CA01a Diagnosis of chronic hypertension**

Check “Yes” (01) if a clinician recorded a diagnosis of chronic hypertension OR a diagnosis of hypertension outside of pregnancy or prior to 20\(^0\) weeks gestation in any earlier pregnancies OR a diagnosis of hypertension that occurred prior to 20\(^0\) weeks gestation in this pregnancy.

Check “No / not Documented” (02) otherwise.

**P5CA01b Diagnosis of chronic proteinuria**

Check “Yes” (01) if a clinician recorded a diagnosis of chronic proteinuria OR a diagnosis of proteinuria that outside of pregnancy or prior to 20\(^0\) weeks gestation in any earlier pregnancies OR a diagnosis of proteinuria that occurred prior to 20\(^0\) weeks gestation in this pregnancy.

Check “No / not Documented” (02) otherwise.
Worst clinician-diagnosed new onset hypertensive disorder of pregnancy during this pregnancy at or after 20\(^0\) weeks EGA through 14 days postpartum? [CHECK ONE:]

No documented new onset maternal hypertensive disorder (01) – Check this box if no clinician has recorded a diagnosis of gestational hypertension, preeclampsia, HELLP syndrome, or eclampsia.

Gestational Hypertension (02) – Check this box if a clinician has recorded a diagnosis of gestational hypertension but no diagnosis of preeclampsia, HELLP syndrome, or eclampsia has been recorded, and complete question P5CA02a. Note: if P5CA01a = “Yes”, flag for adjudication in question P5CE01 and describe in the synopsis on Form P5F.

Preeclampsia (03) – Check this box if a clinician has recorded a diagnosis of preeclampsia or HELLP syndrome but no diagnosis of eclampsia has been recorded, and complete question P5CA02b.

Eclampsia (04) – Check this box if a clinician has recorded a diagnosis of eclampsia.

If worst clinician-diagnosed new onset hypertensive disorder of pregnancy = gestational hypertension, during what period did the gestational hypertension appear? [CHECK ONE]

Check the “Antepartum” box (01) if a clinician recorded the gestational hypertension as antepartum, or otherwise indicated that it developed during the antepartum period (e.g., that it occurred before the onset of labor, spontaneous membrane rupture, or initiation of labor induction, or prior to cesarean delivery if performed prior to the onset of labor, membrane rupture or induction.)

Check the “Intrapartum” box (02) if a clinician recorded the gestational hypertension as intrapartum, or otherwise indicated that it developed during the intrapartum period (e.g., that it occurred after the onset of labor, spontaneous membrane rupture, or initiation of labor induction, or during cesarean delivery, but prior to delivery of the infant and placenta.)

Check the “Postpartum” box (03) if a clinician recorded the gestational hypertension as postpartum, or otherwise indicated that it developed during the postpartum period (e.g., that it occurred after delivery of the infant and placenta and within 14 days of delivery).

Check the “Unspecified” box (04) if none of the above categories apply. Note: if more than one period is recorded, check the box for the earliest.

If worst clinician-diagnosed new onset hypertensive disorder of pregnancy = preeclampsia, what was the severity/type of preeclampsia diagnosed? [CHECK ONE]

Check the “Mild” box (01) if a clinician recorded the preeclampsia as mild and a clinician did not subsequently diagnose the preeclampsia as severe. Note: if either P5CA01a = “Yes” or P5CA01b = “Yes”, flag for adjudication in question P5CE01 and describe in the synopsis on Form P5F.

Check the “Severe” box (02) if a clinician recorded the preeclampsia as severe, or recorded one or more severe features (along the general lines of
nuMoM2b criteria – thrombocytopenia, pulmonary edema, severe hypertension, severe proteinuria, severe headache, epigastric pain, pulmonary edema, thrombocytopenia, oliguria, fetal growth restriction [antenatal diagnosis <10th percentile], or recorded HELLP syndrome. Note: if either P5CA01a = “Yes” or P5CA01b = “Yes”, flag for adjudication in question P5CE01 and describe in the synopsis on Form P5F.

Check the “Superimposed” box (03) if a clinician recorded the preeclampsia as superimposed. Note: if both P5CA01a = “No” and P5CA01b = “No”, flag for adjudication in question P5CE01 and describe in the synopsis on Form P5F.

Check the “Unspecified” box (04) if none of the above categories apply.

Note: If both “Superimposed” and “Severe” (or “Mild”) are recorded in the chart, temporarily resolve according to the baseline conditions and flag for adjudication in question P5CE01 and describe in the synopsis on Form P5F.

P5CA03 Clinician-diagnosed HELLP or incomplete HELLP syndrome. [CHECK ONE:]

Check the “HELLP syndrome” box (01) if a clinician recorded a diagnosis of HELLP or HELLP syndrome.

Check the “Incomplete HELLP syndrome” box (02) if a clinician recorded a diagnosis of incomplete HELLP or incomplete HELLP syndrome.

Otherwise, check the “Neither / not documented” box (03).

Section B. Conditions Documented Prior to This Pregnancy and Outside of Pregnancy or Prior to 200 Weeks Gestation in This or Any Earlier Pregnancies

Questions in this section require documentation of specific criteria in medical records.

P5CB01 Chronic hypertension. Outside of pregnancy or prior to 200 weeks gestation in any earlier pregnancies, was hypertension diagnosed, OR, prior to 200 weeks EGA in this pregnancy, was hypertension present (systolic ≥140 mmHg OR diastolic ≥90 mmHg on two occasions at least 6 hours apart or on one occasion followed by antihypertensive medication therapy)?

Check “Yes” (01) if the criterion is met.

Check “No / not Documented” (02) otherwise.

P5CB02 Baseline proteinuria. Was there baseline proteinuria at the level of:

- total protein ≥ 300 mg in a 24-hour urine collection OR
- total protein ≥ 150 mg in a 12-hour urine collection OR
- protein creatinine ratio ≥ 0.3 g/g (300 mg/g)

documented outside of pregnancy or prior to 200 weeks gestation in this pregnancy or any earlier pregnancies?

Check “Yes” (01) if the criterion is met.

Check “No / not Documented” (02) otherwise.
Section C. Conditions Associated with Hypertensive Disorders of Pregnancy

Indicate which of the conditions were present during this pregnancy at or after 20\textsuperscript{0} weeks gestation through 14 days postpartum as documented by the clinician.

Note: If any condition was present but was possibly unrelated to a hypertensive disorder of pregnancy, flag for adjudication in question P5CE01 and describe in the synopsis on Form P5F.

P5CC01 Pulmonary edema
Check “Yes” (01) if the participant had X-ray confirmed diagnosis of pulmonary edema
Check “No / not Documented” (02) otherwise.

P5CC02 New onset severe headache
Check “Yes” (01) if the condition was present.
Check “No / not Documented” (02) otherwise.

P5CC03 Scotoma
Check “Yes” (01) if the participant had scotoma (a “blind spot” – an area of partial alteration in the field of vision consisting of a partially diminished or entirely degenerated visual acuity surrounded by a field of normal, or relatively well-preserved, vision).
Check “No / not Documented” (02) otherwise.

P5CC04 Cerebral edema
Check “Yes” (01) if the participant had an X-ray confirmed diagnosis of cerebral edema (an excess accumulation of water in the intracellular or extracellular spaces of the brain)
Check “No / not Documented” (02) otherwise.

P5CC05 Epigastric pain
Check “Yes” (01) if the participant had epigastric pain (pain localized to the region of the upper abdomen immediately below the ribs).
Check “No / not Documented” (02) otherwise.

P5CC06 Subcapsular liver hematoma
Check “Yes” (01) if the participant had an X-ray, ultrasound, or surgically confirmed diagnosis of subcapsular liver hematoma.
Check “No / not Documented” (02) otherwise.

P5CC07 Ruptured liver
Check “Yes” (01) if the participant had an X-ray, ultrasound, or surgically confirmed diagnosis of ruptured liver.
Check “No / not Documented” (02) otherwise.

P5CC08 Oliguria (<500 cc urine in 24 hours)
Check “Yes” (01) if there was documented evidence confirming oliguria (<500 cc urine in 24 hours).
Check “No / not Documented” (02) otherwise.

**P5CC09**  
**Fetal growth restriction (diagnosed antepartum)**  
Check “Yes” (01) if there was fetal growth restriction (antenatal diagnosis using <10\textsuperscript{th} percentile estimated fetal weight [EFW] for estimated gestational age [EGA] on ultrasound) without other identifiable cause.  
Check “No / not Documented” (02) otherwise.

**P5CC10**  
**Seizures**  
Check “Yes” (01) if the participant had a seizure during this period.  
Check “No / not Documented” (02) otherwise.

**Section D. Documentation of Clinical Criteria Associated with Hypertensive Disorders**

Questions P5CD01 through P5CD02b1 in this section require documentation of specific criteria in medical records.

**P5CD01**  
**At or after 20\textsuperscript{0} weeks EGA through 14 days postpartum during this pregnancy, did the participant have systolic blood pressure (BP) ≥140 mmHg OR diastolic BP ≥90 mmHg on two occasions at least 6 hours apart or on one occasion followed by antihypertensive medication therapy?**

**Note:** Exclude blood pressures taken during the 2\textsuperscript{nd} stage of labor (from the time the cervix is dilated at 10 cm to the delivery of the baby).

Check “Yes” (01) if the criterion was met and continue to P5CD01a.  
Check “No / not Documented” (02) otherwise and skip to P5CD02.

**P5CD01a**  
**During what period did this first occur? [CHECK ONE]**

Check the “Antepartum” box (01) if this criterion was first met during the antepartum period (e.g., that it occurred before the onset of labor, spontaneous membrane rupture, or initiation of labor induction, or prior to cesarean delivery if performed prior to the onset of labor, membrane rupture or induction.)

Check the “Intrapartum” box (02) if this criterion was first met during the intrapartum period (e.g., that it occurred after the onset of labor, spontaneous membrane rupture, or initiation of labor induction, or during cesarean delivery, but prior to delivery of the infant and placenta.)

Check the “Postpartum” box (03) if this criterion was first met during the postpartum period (e.g., that it occurred after delivery of the infant and placenta).

Check the “Unspecified” box (04) if none of the above categories apply.  
**Note:** if more than one period is recorded, check the box for the earliest.
During the same time frame, did the participant have systolic BP ≥160 mmHg OR diastolic BP ≥110 mmHg on two occasions at least 6 hours apart or on one occasion followed by antihypertensive medication therapy?

**Note:** Exclude blood pressures taken during the 2nd stage of labor (from the time the cervix is dilated at 10 cm to the delivery of the baby).

Check “Yes” (01) if the criterion was met.

Check “No / not Documented” (02) otherwise.

Did the participant have a clinician diagnosis of chronic proteinuria (#A1b = “Yes”) OR documentation of baseline proteinuria (#B2 = “Yes”)?

Check “Yes” (01) if the criterion was met and continue to P5CD02a.

Check “No / not Documented” (02) otherwise and skip to P5CD03.

At or after 20th weeks EGA through 14 days postpartum during this pregnancy, was there a sudden increase in proteinuria (5 times the baseline value, or 2 times a baseline value of ≥5,000 mg/24-hours)?

Check “Yes” (01) if the testing was done and the criterion was met.

Check “No” (02) if the testing was done but the criterion was not met.

Check “Not Documented” (-8) if testing was not done or results were not available.

Did the participant have a clinician diagnosis of chronic hypertension (#A1a = “Yes”) OR documentation of chronic hypertension (#B1 = “Yes”)?

Check “Yes” (01) if the criterion was met and continue to P5CD02b1.

Check “No / not Documented” (02) otherwise and skip to P5CD03.

Excluding blood pressures recorded during the second stage of labor, did the participant have two diastolic blood pressures ≥110 mmHg taken at least four hours apart in the week before delivery

**Note:** Exclude blood pressures taken during the 2nd stage of labor (from the time the cervix is dilated at 10 cm to the delivery of the baby).

Check “Yes” (01) if the criterion was met.

Check “No / not documented in available records” (02) otherwise.

To answer questions P5CD03 through P5CD11, review laboratory findings at or after 20th weeks EGA through 14 days postpartum during this pregnancy. Mark “Not documented” if a test was not done or results are not available.

**Note:** If a result upon which an answer is based was possibly unrelated to a hypertensive disorder of pregnancy, flag for adjudication in question PSCE01 and describe in the synopsis on Form P5F.

Was the highest total protein excretion value from 24-hour urine ≥ 0.3 g (300 mg) [OR 12-hour urine ≥ 0.15 g (150 mg)]?
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

If “Yes” (01), answer P5CD03a.
Else skip to P5CD04.

P5CD03a  
Highest total protein excretion value from 24-hour urine ≥ 5 g (5000 mg) 
OR from 12-hour urine ≥ 2.5 g (2500 mg)?
Check “Yes” (01) if the criterion was met.
Check “No” (02) if criterion was not met.

P5CD04  
Was the highest urine protein-creatinine ratio ≥ 0.3 g/g (300 mg/g)?
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

P5CD04a  
Check if the protein-creatinine ratio should override the 24-hour urine
Check the box (01) if the timing of the 24-hour urine protein and protein-creatinine ratio measurements relative to the timing of the worst nuMoM2b-defined maternal hypertensive disorder of pregnancy is such that the protein-creatinine ratio should override the 24-hour urine measurement; e.g., if the protein-creatinine measurement is significantly more proximate to the onset of the worst hypertensive disorder. If the answer is unclear, discuss with your PI or his/her designee.

P5CD05  
What was the highest dipstick urine protein value?  [CHECK ONE]
Check “0 or trace” (01), 1+ (02), 2+ (03), 3+ (04), or 4+ (05) as appropriate if dipstick testing results were recorded.
Check “Not documented” (-8) if testing was not done or results were not available.

P5CD05a  
Check if the dipstick should override the 24-hour urine
Check the box if the timing of the 24-hour urine protein and urine protein dipstick measurements relative to the timing of the worst nuMoM2b-defined maternal hypertensive disorder pregnancy is such that the dipstick urine protein value should override the 24-hour urine measurement; e.g., if the dipstick urine protein is significantly more proximate to the onset of the worst hypertensive disorder. If the answer is unclear, discuss with your PI or his/her designee.

P5CD06  
Was the lowest serum platelet count < 100,000/mm³?
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

P5CD07  **Was hemolysis ever documented on peripheral smear?**
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

P5CD08  **Was the highest serum lactate dehydrogenase (LDH) ≥600 IU/L?**
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

P5CD09  **Was the highest serum total bilirubin ≥1.2 mg/dL (20 µmol/L)?**
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

P5CD10  **Was the highest serum AST (SGOT) ≥100 IU/L?**
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

P5CD11  **Was the highest serum creatinine >1.1 mg/dL?**
Check “Yes” (01) if the testing was done and the criterion was met.
Check “No” (02) if the testing was done but the criterion was not met.
Check “Not Documented” (-8) if testing was not done or results were not available.

**Section E. Need for Adjudication**

Section E contains one question, whether the data need adjudication. This question should be answered “Yes” (01) in the following situations:

- One or more conditions reported in Section C or criteria met in Section D are considered to be possibly unrelated to a new onset hypertensive disorder of pregnancy.

- The timing of one or more conditions reported in Section C or criteria met in Section D is considered to be not relevant to a possible diagnosis of a new onset hypertensive disorder of pregnancy.

- Any of the miscellaneous criteria for adjudication mentioned in Section 14.10.2 are met.
Any other reason or uncertainty for which the chart abstractor believes an adjudication should be done.

The adjudication process will be performed by the abstractor and the PI or his/her designee. The results and supporting information will be recorded on Form P5F (“Subsequent Pregnancy – Record of Adjudication for Maternal Hypertensive Disorder”).

In addition, a hypertensive diagnoses report will compute nuMoM2b diagnoses of hypertensive disorders that are supported by the data recorded in Sections B-D and will compare these with the clinician diagnoses in Section A. This report will indicate whether there are certain discrepancies in the diagnoses that require submission of Form P5F, regardless of the answer to question E1 on Form P5C. See Section 14.14.13 (Form P5F) for additional detail about the report.

14.11 Form P5D: Subsequent Pregnancy Loss (<200 Weeks EGA)

14.11.1 General Instructions
Complete this form for each fetal loss before 200 weeks estimated gestational age identified on Form P5A. For answers that are not simple check boxes, enter -8 if an answer is not documented in the chart. This form records information related to the pregnancy outcome and provides information that might relate to the pregnancy loss. Since this form is completed for each fetus lost during the pregnancy, including documented vanishing twins, there may be more than one form for a given pregnancy.

14.11.2 Question-by-Question Specifications
At the top of the form, enter the participant’s Study ID, the date the pregnancy ended (i.e., date of the last outcome listed in the table for Section B, Question 4 in form P5A), the fetus number of the fetus from this pregnancy for whom the form is being completed (from Column 1 of the table in Section B, Question 4 of form P5A for this pregnancy), the nuMoM2b-HHS staff ID of the person finalizing and verifying completion of the form, and the date the form was completed in mm/dd/yyyy.

Section A. Pregnancy Outcome Information

P5DA01 Spontaneous fetal demise
Mark “Yes” if the record documents that the fetal termination was due to a spontaneous fetal demise at less than 200 weeks estimated gestational age. Otherwise, mark “No / not documented.”

Answer questions P5DA01a through P5DA01b2, only if the fetal termination was due to a spontaneous fetal demise. If the fetus was terminated by a medical procedure, skip to P5DA02.

P5DA01a Enter the date the fetal demise for this fetus was first diagnosed in available records in the format mm/dd/yyyy. If the date is unknown, enter -8 in the
month field. Range: P5DA01a_M (01-12, -8); P5DA01a_D (01-31, -8); P5DA01a_Y (2010-2017, -8).

P5DA01b1 If an ultrasound was done to confirm the fetal demise, indicate the date the ultrasound was performed in the format mm/dd/yyyy. If no ultrasound is reported in available records, enter “-8” as the month of the ultrasound and skip to P5DA02. Range: P5DA01b1_M (01-12, -8); P5DA01b1_D (01-31, -8); P5DA01b1_Y (2010-2017, -8).

P5DA01b2 Record the gestational age calculated by the ultrasound machine on the date of the ultrasound at the time the fetal demise was diagnosed as weeks and days. Enter “-8” for weeks if the gestational age calculated by the machine was not recorded. (Range for Weeks: -8; 6-19; Range for Days: 0-6)

P5DA02 Indicate whether any congenital anomalies were identified by marking the box for “Yes” or the box for 'No / not documented.” If “Yes,” specify the anomalies on one or more of the next three lines. If “No,” skip to question P5DB01.

P5DA02a1 Describe the anomaly. (Similar instructions for P5DA02b1 and P5DA02c1)

P5DA02a2 Code the anomaly described on line “a” using Coding List 1 on the back of the form. (Similar instructions for P5DA02b2 and P5DA02c2)

Section B. Workup

In P5DB01, indicate whether each of the conditions listed was associated with the pregnancy loss as noted in the records. “Yes” indicates that the condition is noted in the available records for this fetus. “No / not documented” indicates that the condition was not noted in the available records for this fetus.

P5DB01a **Chromosomal abnormality:** Mark "yes" if any chromosomal abnormality has been detected. Another word for chromosomal is "karyotypic;" These abnormalities are detected with standard cytogenetic analyses. "Yes" will also apply if there is a genetic microarray analysis performed with abnormal results detected. These results are often quite complex in their nomenclature. If in question, review the results with your site principal investigator. Mark “No / not documented” if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01b **Structural anomaly:** Mark "yes" if any major structural anomaly was detected and noted. This can range from a neural tube defect (a spectrum of disorders reflecting lack of closure of the neural tube, which forms the spinal cord and the central nervous system, including anencephaly [absence of the fetal head/brain] to spina bifida), a heart defect, limb abnormalities such as club feet or extra digits (known as polydactyly), an open abdominal wall defect (such as gastrochisis or omphalocele), among other. If in question, review the results with your site principal investigator. Mark “No / not documented" if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01c **Cervical insufficiency:** Mark "yes" if the participant was diagnosed with cervical insufficiency. The term "cervical incompetence" is synonymous. This is the term used to describe a presumed structural weakness of cervical tissue that causes or contributes to the loss of an otherwise healthy pregnancy. It is often marked by painless cervical dilation leading to birth in
the second trimester. Mark “No / not documented” if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01d  Preterm premature rupture of membranes: Mark “yes” if the patient was diagnosed with spontaneous preterm premature rupture of membranes. This is often diagnosed after participant complaints of “gush of fluid,” per vagina, and is confirmed by a combination of physical examination and laboratory evaluations. These include performance of a sterile speculum examination in which the amniotic fluid is seen to pool in the vagina (“pooling”), or by gross physical examination where the amniotic fluid is seen to leak from the vagina onto the patient’s perineum (or even the bedclothes), plus laboratory evaluation of the fluid in which a pH change is seen on nitrazine paper (turning paper from yellow to blue) and/or the fluid is seen to create a “ferning” pattern on the microscope slide. Other biochemical tests such as the Amnisure™ test for placental alpha microglobulin-1 may also be used. Answer choices: Mark “No / not documented” if this diagnosis was not seen in available records. Yes (01), No / not documented (02).

P5DB01e  Bleeding/subchorionic hemorrhage: Mark “yes” if the pregnancy loss was associated with a clinically significant amount of vaginal bleeding that was presumably from a placental source. The diagnosis of a "subchorionic hematoma" may have been made prior to the pregnancy loss with the use of ultrasound. This would reveal itself as the presence of an irregular mass, usually at the edge of a placenta, that is presumed to be due to an abnormal separation of the placenta from the underlying uterus. Mark “No / not documented” if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01f  Intrauterine infection: Mark “yes” if a documented intrauterine infection was known to precede the pregnancy loss and/or there was evidence of infection at the time of delivery. A documented infection preceding the pregnancy loss would most likely have been diagnosed with the use of an amniocentesis and the results from the amniotic fluid Gram stain for bacteria or fungus and/or amniotic fluid bacteriological/fungal cultures revealed the presence of a causative organism. Histologic evaluation of the placenta and membranes could also demonstrate the presence of infection and may identify some of the forms of the bacterial/fungal agents. Documented viral or placental infections would be ascertained by amniotic fluid testing, most often polymerase chain reaction (PCR) testing for viruses such as cytomegalovirus (CMV) or toxoplasmosis. Often if a congenital viral or parasitic infection is suspected, maternal serologic testing will precede any amniocentesis for confirmation. Because of the wide variation in potential etiologies of intrauterine infection, if questions, consult the site principal investigator. Mark “No / not documented” if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01g  Severe medical disease, specify: Mark “Yes” if the pregnancy loss less than 20 weeks was due to a severe medical complication. An example of this would be a pregnancy termination performed in a mother with Eisenmenger’s Syndrome, a complex cardiac disease process in which the maternal mortality rates are very high. If “yes,” specify the maternal disease process in open text (P5DB01g_sp). Mark “No / not documented” if this diagnosis was
not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01h  **Uterine anomaly, specify:** Mark “yes” if the patient was known to have a uterine or "Mullerian" abnormality or defect. This can run a range of abnormalities including a uterine didelphys (duplicated uteri and cervixes), bicornuate uterus, unicornuate uterus, uterine septum. If “yes,” specify the type of uterine anomaly as open text (P5DB01h_sp). Mark “No / not documented” if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01i  **Leiomyomas:** Mark "yes" if the patient was known to have uterine leiomyomas, also known as fibroids, or fibroid tumors. Mark “No / not documented” if this diagnosis was not seen in available records. Answer choices: Yes (01), No / not documented (02).

P5DB01j  **Other, specify:** Mark “yes” if another condition was known to be associated with the patient's pregnancy loss, including a documented vanishing twin. Specify the condition as open text (P5DB01j_sp). For a vanishing twin, specify “vanishing twin.” Mark “No / not documented” if no other diagnosis was seen in available records. Answer choices: Yes (01), No / not documented (02).

14.12 Form P5E: Subsequent Stillborn Workup

14.12.1 General Instructions
This form is completed for each stillbirth occurring at 200 weeks project estimated gestational age or after. This form records information related to the fetal stillbirth. Since this form is completed for each stillborn fetus for the pregnancy, there may be more than one form for a given pregnancy.

14.12.2 Question-by-Question Specifications
At the top of the form, enter the participant’s Study ID, the date the pregnancy ended (i.e., date of the last outcome listed in the table for Section B, Question 4 in form P5A), the fetus number of the fetus from this pregnancy for whom the form is being completed (from Column 1 of the table in Section B, Question 4 of form P5A for this pregnancy), the nuMoM2b staff ID of the person finalizing and verifying completion of the form, and the date the form was completed in mm/dd/yyyy.

**Section A.  Pregnancy Outcome**

P5EA01  **Type of stillbirth**
Mark “Antepartum” if the fetal death occurred prior to the onset of labor. Mark “Intrapartum” if death occurred after the onset of labor, i.e., fetal heart motion was documented prior to labor, but disappeared sometime during labor or at birth. Mark “Unknown” if the record does not indicate when the fetal demise occurred. Answer choices: Antepartum (01), Intrapartum (02), Unknown (-8).
Section B. Workup

All available lab reports from the current pregnancy for the participant should be reviewed in order to complete this section.

P5EB01 Autopsy

Mark “Yes” (01) or “No / not documented” (02) to indicate if a fetal autopsy was performed. It may take a while for the report of the autopsy results to become available. Therefore, mark “Yes” if an autopsy was requested, and the fetus was sent to pathology.

P5EB02 Final cause of stillbirth

This question is completed by the site PI, lead investigator at a subsite, or an experienced MD that they appoint to answer the question. Use open text to describe the final cause of the stillbirth as described in the medical record. If the cause is unknown, so indicate.

The site PI, lead investigator at the subsite, or their designee should also complete the INCODE form developed during the Stillbirth Collaborative Research Network (SCRN) for each stillborn infant. Instructions for completion of this form are available from the DCAC PI and co-PI.

Site coordinators are responsible for ensuring that these sections are completed for each identified stillborn infant.

14.13 Form P5F: Subsequent Pregnancy – Record of Adjudication for Maternal Hypertensive Disorder

14.13.1 General Instructions

The abstractor and the site PI or his/her designee completes the Subsequent Pregnancy – Record of Adjudication for Maternal Hypertensive Disorder Form for each pregnancy reported on Form P5C for which:

1. the abstractor (coordinator or research assistant) indicates in question E1 on Form P5C that the case requires adjudication; AND/OR
2. the P5F form is required as indicated on the hypertensive diagnoses report.

No more than one form is completed per pregnancy.

Regarding criterion #1, reasons for requesting adjudication on Form P5C are discussed under “Section E” at the end of Section 14.10.2.

Regarding criterion #2, the hypertensive diagnoses report will compute nuMoM2b defined diagnoses of baseline conditions, worst new onset hypertensive disorder, and HELLP that are supported by the data in Form P5C Sections B-D and will compare these with the clinician diagnoses recorded in Form P5C Section A. If no adjudication is done, the following default diagnoses will be used in data analyses.

For baseline conditions:

- If there is either a nuMoM2b or a clinician diagnosis of chronic hypertension, the default diagnosis will be chronic hypertension; otherwise, no chronic hypertension.
• If there is either a nuMoM2b or a clinician diagnosis of baseline proteinuria, the default
  diagnosis will be baseline proteinuria; otherwise, no baseline proteinuria.

For the **worst new onset hypertensive disorder** and for **HELLP**:

• If the nuMoM2b diagnosis is *more severe than* the clinician diagnosis, the **nuMoM2b
diagnosis** will be accepted by default.

• If the nuMoM2b diagnosis is *the same as* the clinician diagnosis then the
  **nuMoM2b/clinician diagnosis** will be the default.

• If the nuMoM2b diagnosis is *less severe* than the clinician diagnosis and **no prenatal
  records were available to be abstracted** (Form P5A question 2c = “No/NA” [02]), the
  **clinician diagnosis** will be the default.

• If the nuMoM2b diagnosis is *less severe* than the clinician diagnosis and **prenatal records were available to be abstracted** (Form P5A question 2c = “Yes” [01]) the **nuMoM2b diagnosis** will be the default.

  **NOTE:** This last circumstance will trigger a requirement for completion of Form P5F. This will be indicated on the hypertensive diagnoses report.

These criteria will be evaluated separately for the worst hypertensive diagnosis and HELLP (but taking into account that the latter may influence the former).

The hypertensive diagnoses report will indicate whether there are certain discrepancies in the diagnoses that require submission of Form P5F, regardless of the answer to question E1 on Form P5C. The specific discrepancies for a given case will be listed in the report.

The clinician, nuMoM2b, and default diagnoses in the hypertensive diagnoses report should be reviewed prior to any adjudication, even if no discrepancies were noted (i.e., the need for adjudication was indicated only by a “Yes” (01) answer to question E1 on Form P5C).

When the last condition bulleted above occurs (i.e., nuMoM2b diagnosis less severe and prenatal records available) a judgement call regarding the completeness of the prenatal records will be required. If **all** of the following are true:

• the last criterion above is listed on the report as the only discrepancy requiring submission of Form P5F;

• there are no other reasons to adjudicate the case (i.e., Form P5C, Question E1 is “No” (02)); **AND**

• the prenatal records were complete, or judged to be sufficiently complete that the default (i.e., nuMoM2b) diagnosis in this setting should be accepted,

then check the box labeled “Check if adjudication not required and STOP” in the header of P5F Section A. This cancels the remainder of the adjudication and will skip the keyer out of the form. This is the **only** circumstance in which this box should be checked. Otherwise, the adjudication proceeds, and the clinical synopsis (Section A), the rationale for the adjudicated diagnoses (Section A), and the adjudicated diagnoses (Section B) are recorded. **Note:** The adjudication process will evaluate the case using nuMoM2b definitions, not ACOG 2013.

Data analyses will use the default diagnoses, unless an adjudication is performed and submitted on Form P5F, in which case the adjudicated diagnoses reported in Section B of Form P5F will be used.
14.13.2 Question-by-Question Specifications

Before asking the PI or his/her designee to complete this form, the coordinator should enter the required information in the form header. At the top of the form, enter the participant’s Study ID, the date that the pregnancy being abstracted ended (format mm/dd/yyyy; in case of multiple gestation, use the latest date listed in P5A, Section B, Question 4, column 2), the ID of the person finalizing and verifying completion of the form, and the date the form was completed in mm/dd/yyyy format.

Section A. Adjudication

P5FA_check  
Check if adjudication not required and STOP

Check the box if all of the following are true:

- the last criterion above is listed on the report as the only discrepancy requiring submission of Form P5F;
- there are no other reasons to adjudicate the case (i.e., Form P5C, Question E1 is “No” (02)); AND
- the prenatal records were complete, or judged to be sufficiently complete that the default (i.e., nuMoM2b) diagnosis in this setting should be accepted,

P5FA01  
Synopsis

The abstractor prepares an initial synopsis in free text explaining the issues and rationale for requesting adjudication. This may subsequently be revised by the abstractor and/or the PI or his/her designee.

P5FA02  
Rationale for adjudicated diagnoses

The PI or his/her designee provides a rationale for the adjudicated diagnosis(es) in free text.

Section B. Adjudicated Diagnoses

Note: The adjudication process will evaluate the case using nuMoM2b definitions, not ACOG 2013.

P5FB01  
Chronic hypertension (prior to pregnancy or before 20th weeks gestation)

Check “Yes” (01) if there is an adjudicated diagnosis of chronic hypertension.
Check “No / Not documented” (02) otherwise.

P5FB02  
Baseline proteinuria (at preeclamptic levels prior to pregnancy or before 20th weeks gestation)

Check “Yes” (01) if there is an adjudicated diagnosis of baseline hypertension.
Check “No / Not documented” (02) otherwise.
Worst new onset hypertensive disorder of pregnancy at or after 20 weeks gestation during this pregnancy through 14 days postpartum [CHECK ONE AND ANSWER RELEVANT SUBPARTS]

No documented new onset maternal hypertensive disorder (01) – Check this box if no adjudicated diagnosis of gestational hypertension, preeclampsia, HELLP syndrome, or eclampsia has been made.

Gestational Hypertension (02) – Check this box if there is an adjudicated diagnosis of gestational hypertension but no adjudicated diagnosis of preeclampsia, HELLP syndrome, or eclampsia has been made; and complete question P5FB03a.

Preeclampsia (03) – Check this box if there is an adjudicated diagnosis of preeclampsia or HELLP syndrome but no adjudicated diagnosis of eclampsia has been made; and complete question P5CA03b.

Eclampsia (04) – Check this box if there is an adjudicated diagnosis of eclampsia.

If adjudicated worst clinician-diagnosed new onset hypertensive disorder of pregnancy = gestational hypertension, during what period did the gestational hypertension appear? [CHECK ONE]

- Check the “Antepartum” box (01) if it has been adjudicated that the gestational hypertension developed during the antepartum period (e.g., that it occurred before the onset of labor, spontaneous membrane rupture, or initiation of labor induction, or prior to cesarean delivery if performed prior to the onset of labor, membrane rupture or induction.)

- Check the “Intrapartum” box (02) if it has been adjudicated that the gestational hypertension developed during the intrapartum period (e.g., that it occurred after the onset of labor, spontaneous membrane rupture, or initiation of labor induction, or during cesarean delivery, but prior to delivery of the infant and placenta.)

- Check the “Postpartum” box (03) if it has been adjudicated that the gestational hypertension developed during the postpartum period (e.g., that it occurred after delivery of the infant and placenta).

- Check the “Unspecified” box (04) if none of the above categories apply.

If adjudicated worst clinician-diagnosed new onset hypertensive disorder of pregnancy = preeclampsia, what was the adjudicated severity/type of preeclampsia diagnosed? [CHECK ONE]

Note: Make sure the adjudicated severity/type of preeclampsia is consistent with the adjudicated baseline diagnoses in P5FB01 and P5FB02 above.

- Check the “Mild” box (01) if the severity/type of preeclampsia is adjudicated as mild.

- Check the “Severe” box (02) if the severity/type of preeclampsia is adjudicated as severe, involving one or more adjudicated nuMoM2b criteria for severe preeclampsia – thrombocytopenia, pulmonary edema, severe hypertension, severe proteinuria, severe headache, epigastric pain, pulmonary edema, thrombocytopenia, oliguria, fetal growth restriction.
[antenatal diagnosis <10th percentile]), or adjudicated diagnosis of HELLP syndrome.

Check the “Superimposed” box (03) if the adjudicated severity/type of preeclampsia is superimposed preeclampsia.

Check the “Unspecified” box (04) if none of the above categories apply.

**Diagnosis of HELLP syndrome. [CHECK ONE:]**

Check the “HELLP syndrome” box (01) if there is an adjudicated diagnosis of HELLP syndrome.

Check the “Incomplete HELLP syndrome” box (02) if there is an adjudicated diagnosis of incomplete HELLP.

Otherwise, check the “Neither / Not documented” box (03).