



- Black
- White
- Asian
- Other \_\_\_\_\_

**c. Ethnicity (tick one)**

- Hispanic
- Not Hispanic
- Native Population
- Other \_\_\_\_\_

**d. Infant gender (tick one)**

- Male
- Female

**e. Mode of delivery (tick one)**

- Vaginal
- C-section:
- Other: \_\_\_\_\_

**f. Singleton pregnancy (tick one)**

- Yes
- No

**g. Parity (fill 1-4 each with full number)**

1. Prior Term Pregnancies \_\_\_\_\_ (number)
2. Prior Preterm Pregnancies (<37 wk) \_\_\_\_\_ (number)
3. Abortions/miscarriage (<20 wk) \_\_\_\_\_ (number)
4. Born Alive \_\_\_\_\_ (number)

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**GESTATIONAL AGE ASSESSMENT**

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**4. Recorded gestational age (from chart)**

\_\_\_\_\_ (Number: weeks/days)

**5. How was gestational age assessed:**

- Antenatal Maternal US
- LMP
- Infant Exam,
- Other (describe) \_\_\_\_\_

**6. Elements of GA available in the record (tick one option on each line for a-l)**

	Recorded	NOT recorded	Incomplete/uncertain	Comments/Issues
a. Intrauterine insemination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Embryo transfer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Certain LMP (LMP known)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Uncertain LMP (LMP not known)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e. First trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f. Second trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
g. Third trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
h. Fundal height (any)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
i. Fundal height in 2 <sup>nd</sup> trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j. Maternal physical exam in 1 <sup>st</sup> trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
k. Birth weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
l. Newborn GA by physical exam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

**7. Assessment of Gestational Age LOC based on GAIA Definition (Use Case Definition**

**Checklist:see appendix 2):**

a. Level of certainty \_\_\_\_\_ (1X,2X,3X, or U: unable to assess)

b. If unable to assign GA LOC, describe the reason(s):

Reason \_\_\_\_\_

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### CASE DEFINITION SPECIFIC VARIABLES

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#### 8. Elements of the Non Reassuring Fetal Status case definition in maternal clinical or study record (please tick each line)

Parameter available	Evidence in Medical Record or Study MOP/Protocol			Comments
	Yes	No	Uncertain	
a. Continuous cardiotocography	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Intermittent cardiotocography only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Category of rating of fetal heart rate strip based on NICHD criteria <sup>1</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Category III fetal heart rate (FHR) tracings : Absent baseline FHR variability AND one of the following: recurrent late decelerations recurrent variable deceleration bradycardia (<110 bpm) OR Sinusoidal Pattern	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Umbilical cord blood analysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Umbilical cord blood analysis with acidosis pH<7.0, and Base deficit >12mmol/L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. FHR detected via intermittent auscultation with Baseline Fetal heart rate <110 or >160 bpm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. FHR detected via intermittent auscultation with presence of repetitive or prolonged (>3 min) decelerations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. FHR detected via intermittent auscultation more than 5 contractions in a 10 min period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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**QUALITY ASSESSMENT CASE DEFINITION**

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**9. Case abstractor's best assessment of LOC for Non Reassuring Fetal Status is (Use Case Definition Checklist in appendix 1 ):**

a. Level of certainty \_\_\_\_\_ (1,2,3, or U: unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason \_\_\_\_\_

**10. PI's assessment of LOC for Non Reassuring Fetal Status (Use Case Definition Checklist in appendix 1):**

a. Level of certainty \_\_\_\_\_ (1,2,3, or U: unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason \_\_\_\_\_

**11. Other comments:**

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<sup>1</sup>NICHD Three-tier Fetal Heart Rate Interpretation System (2008)

FHR Designation	Description
<b>Category I tracing</b>	<p><i>Baseline heart rate:</i> 110-160 bpm</p> <p><i>Variability:</i> Moderate</p> <p>No late decelerations</p> <p>Early decelerations may be present or absent</p> <p>Accelerations may be present or absent</p>
<b>Category II tracing</b>	<p>FHR tracing does not meet criteria for category I or category III</p>
<b>Category III tracing</b>	<p>1)<i>Variability:</i> Absent FHR baseline variability</p> <p>AND any of the following: Recurrent late decelerations Recurrent variable decelerations Bradycardia (FHR&lt;110 bpm)</p> <p>OR</p> <p>2)Sinusoidal pattern</p>







**Appendix 1: Non Reassuring Fetal Status**  
**Guide for LOC assignment for Non Reassuring Fetal Status (check all that are present)**

Non Reassuring Fetal Status requires some type of fetal heart rate monitoring during labor.

**Case definition of Non Reassuring Fetal Status**

**Level 1 of diagnostic certainty**

- 1. Continuous cardiotocography AND
  - 2. Absent fetal baseline variability AND
  - 3. Recurrent late decelerations
- OR
- 3. Recurrent variable decelerations
- OR
- 3. Sinusoidal pattern
- AND
- 4. Umbilical cord blood analysis consistent with metabolic acidosis (pH<7.0 and Base deficit >12 mmol/L)

**Level 2 of diagnostic certainty**

- 1. Continuous cardiotocography AND
  - 2. Absent fetal baseline variability AND
  - 3. Recurrent late decelerations
- OR
- 3. Recurrent variable decelerations
- OR
- 3. Sinusoidal pattern

**Level 3 of diagnostic certainty**

- 1. Intermittent auscultation AND
  - 2. Baseline FHR < 110 bpm or >160 bpm
- OR
- 2. Presence of repetitive or prolonged (>3 min) decelerations
- OR
- 2. More than 5 contractions in a 10 min period

**Insufficient evidence:**

- 1. No fetal monitoring

## Appendix 2:

### Gestational Age Assessment Guide

#### Definitions of terms used:

**Intrauterine insemination (IUI)** – A procedure in which a fine catheter is inserted through the cervix into the uterus to deposit a sperm sample directly into the uterus, to achieve fertilization and pregnancy.

**Embryo transfer** – The procedure in which one or more embryos are placed in the uterus or fallopian tube.

#### **Ultrasound (U/S):**

- 1st trimester ( $\leq 13 \frac{6}{7}$  weeks).
- 2nd trimester scan ( $14 \frac{0}{7}$ – $27 \frac{6}{7}$  weeks).
- 3rd trimester ( $28 \frac{0}{7}$  + weeks).

**LMP** (last menstrual period) – GA is calculated from the first day of the mother’s LMP. If LMP and U/S do not correlate, default to U/S GA assessment.

**\*Certain LMP:** (LMP date + 280 days): Use LMP if within 7 days at  $\leq 14$  weeks; within 14 days at  $\leq 26$  weeks; within 21 days beyond 26 weeks.

**\*Uncertain LMP – first trimester** ( $\leq 13 \frac{6}{7}$  weeks by LMP): Use the approximate date of the last menstrual period (LMP) if corroborated by physical exam, or a first trimester ultrasound. If there is a discrepancy of  $>7$  days between the LMP and the first trimester ultrasound, the ultrasound-established dates will take preference over LMP for gestational age dating.

**\*Uncertain LMP – second trimester** ( $14 \frac{0}{7}$ – $27 \frac{6}{7}$  weeks by LMP): Use the approximate date of the LMP if corroborated by physical exam including fundal height, or a second trimester ultrasound. If there is a discrepancy of  $>10$  days between the LMP and the second trimester ultrasound, the ultrasound-established dates will take preference over LMP for GA dating.

**\*Uncertain LMP – third trimester**  $>28$  weeks – third trimester ultrasound.

**\*No LMP date:** If menstrual dates are unknown, the ultrasound established dates will be used for gestational age dating or 2nd trimester fundal height and/or newborn physical examination.

**Pregnancy symptoms**– nausea, fatigue, tender swollen breasts, frequent urination.

**Antenatal Physical Examination**– pelvic bimanual examination confirming enlarged uterus.

**Newborn Physical Examination**– New Ballard Score – physical and neurological assessment.

**Fundal Height (FH)** in cm

**Birth Weight (BW) in grams**

**GA Levels of Certainty (check all that are present)**

**Level 1**

- 1. Certain LMP\* or intrauterine insemination (IUI) date or embryo transfer (ET) date with confirmatory 1st trimester scan ( $\leq 13\ 6/7$  weeks).

OR

- 2. 1st trimester scan ( $\leq 13\ 6/7$  weeks).

**Level 2A**

- 1. Certain LMP\* with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks). If LMP and U/S do not correlate, default to U/S GA assessment.

OR

- 2. Certain LMP\* with 1st trimester physical examination.

**Level 2B**

- Uncertain LMP with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks).

**Level 3A**

- 1. Certain LMP with 3rd trimester scan – 28 0/7 weeks +.

OR

- 2. Certain LMP with confirmatory 2nd trimester FH.

OR

- 3. Certain LMP with birth weight.

OR

- 4. Uncertain LMP with 1st trimester physical examination.

**Level 3B**

- 1. Uncertain LMP with FH.

OR

- 2. Uncertain LMP with newborn physical assessment.

OR

- 3. Uncertain LMP with Birth weight.

