

**NVPO Definitions Project**  
**DATA COLLECTION FORM v0.9 Feb15, 2018**  
**Fetal Growth Restriction (FGR)**

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**ADMINISTRATIVE INFORMATION**

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**Initials of person performing the review:** \_\_ \_\_

**Outcome code:** FGR

**Country code:** US, AU, UK: \_\_ \_\_

**Site code:** BC, CC, EM, UW, MO, SG, SU: \_\_ \_\_

**Origin code** CT=clinical trial MR= medical record: \_\_ \_\_

**Subject ID number** FGR                                      
Country Site Origin Number (starting with 01)

**Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of FGR:**  
(from case identification log): \_\_\_\_\_

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**COMMON VARIABLES**

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**1. If clinical trial (tick and list study drug/vaccine):**

- Vaccine \_\_\_\_\_
- Drug \_\_\_\_\_
- Epidemiologic \_\_\_\_\_
- Other \_\_\_\_\_

**2. Year of event:** \_\_\_\_\_ (full year)

**3. General pregnancy variables**

**a. Maternal Age (years)**

\_\_\_\_\_ (number)

**b. Race (tick one)**

- 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,4,5 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. Components of the FGR case definition in clinical record:

Parameter	Evidence in Medical Record or Study MOP/Protocol			Comments
	Yes	No	Uncertain	
a. Estimated fetal weight below 3% using locally accepted growth curve	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Estimated fetal weight below 10% using locally accepted growth curve	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Oligohydramnios present	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Absent or reversed end-diastolic flow of the umbilical artery doppler	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. NO FINDINGS of absent or reversed end-diastolic flow of the umbilical artery or oligohydramnios	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<sup>1</sup> oligohydramnios is defined as a decreased amniotic fluid volume as defined by amniotic fluid index less than 8 cm or deepest vertical pocket less than 2 cm in the presence of intact membranes without concern for fetal anomalies contributing to its etiology

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### QUALITY ASSESSMENT CASE DEFINITION

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#### 9. Case abstractor's best assessment of LOC for FGR is (Use Case Definition Checklist in appendix 1):

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

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

Reason \_\_\_\_\_

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

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

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

Reason \_\_\_\_\_

**11. Other comments:**

\_\_\_\_\_

**Appendix 1: Fetal Growth Restriction (FGR)**  
**Guide for LOC assignment for Fetal Growth Restriction (check all that are present)**

Fetal Growth Restriction (FGR) is a sonographic finding made prior to birth. The FGR workgroup felt ultrasound during pregnancy was mandatory to be able to determine a case of FGR

**Case definition of Fetal Growth Restriction**

**For all LEVELS:**

- . Ultrasound performed during pregnancy

**Level 1a of diagnostic certainty**

- 1. Level 1 evidence of pregnancy dating (see gestational age algorithm) AND
  - 2. Estimated fetal weight below 3% using locally-accepted growth curve
- OR
- 2. Estimated fetal weight below 10% using locally-accepted growth curve AND
  - 3. Absent or reversed end-diastolic flow of the umbilical artery Doppler
- OR
- 3. Oligohydramnios<sup>1</sup>

**Level 1b of diagnostic certainty**

- 1. Level 1 evidence of pregnancy dating (see gestational age algorithm) AND
  - 2. Estimated fetal weight below 10% using locally-accepted growth curve AND
  - 3. No findings of absent or reversed end-diastolic flow of the umbilical artery Doppler
- OR
- 3. No findings of oligohydramnios<sup>1</sup>

**Level 2a of diagnostic certainty**

- 1. Level 2 evidence of pregnancy dating (see gestational age algorithm) AND
  - 2. Estimated fetal weight below 3% using locally-accepted growth curve
- OR
- 2. Estimated fetal weight below 10% using locally-accepted growth curve AND
  - 3. Absent or reversed end-diastolic flow of the umbilical artery Doppler
- OR
- 3. Oligohydramnios<sup>1</sup>

**Level 2b of diagnostic certainty**

- 1. Level 2 evidence of pregnancy dating (see gestational age algorithm) AND

- 2. Estimated fetal weight below 10% using locally-accepted growth curve AND
  - 3. No findings of absent or reversed end-diastolic flow of the umbilical artery Doppler
- OR
- 3. No findings of oligohydramnios<sup>1</sup>
- OR
- 4. Level 1 evidence of pregnancy dating (see gestational age algorithm) AND
  - 5. Estimated fetal weight below 10% using locally-accepted growth curve AND
  - 6. No findings of oligohydramnios AND
  - 7. Inability to assess umbilical artery Doppler

<sup>1</sup> oligohydramnios is defined as a decreased amniotic fluid volume as defined by amniotic fluid index less than 8 cm or deepest vertical pocket less than 2 cm in the presence of intact membranes without concern for fetal anomalies contributing to its etiology

**Insufficient evidence:**

- 1. Absence of ultrasound for use in assessment of estimated fetal weight during pregnancy

## 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 ( $\leq 13 \frac{6}{7}$  weeks).

OR

- 2. 1st trimester scan ( $\leq 13 \frac{6}{7}$  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.

