NVPO Definitions Project DATA COLLECTION FORM v1.0 June 28, 2018

Fetal Growth Restriction (FGR)

ADMINISTRATIVE INFORMATION

Initials of person per	rforming 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):					
	<i></i>				
	COMMON VARIABLES				
1. If case from clinic	al trial (tick and list study drug/vaccine):				
□ Vaccin	e				
☐ Drug _					
☐ Epid er	niologic				
□ Other					
2. Year of event:	(full year)				

a. Maternal Age (whole years) at time of delivery _____ (number if uknown fill UNK) b. Race (tick one, please tick other and state UNK, if unknown/uncertain) Black White Asian Other ____ c. **Ethnicity** (tick one, please tick other and state UNK if unknown/uncertain) d. □ Hispanic **Not Hispanic Native Population** Other _____ e. Infant gender (tick one, please tick other and state UNK if unknown/uncertain) Male Female Other f. Mode of delivery (tick one, please tick other and state UNK if unknown/uncertain) Vaginal C-section: Other: g. Singleton pregnancy (tick one, please tick other and state UNK, if unknown/uncertain) Yes No Other: _____

3. General pregnancy variables

	h.	Parity (fill 1-4 each with full number based on the status at start of this pregnancy). Gravidity is defined as the number of times that a woman has been pregnant and parity is defined as the number of times that she has given birth to a fetus, regardless of whether the child was born alive or was stillborn
		(fill what you see in chart, if absent state UNK)
		Gravidity/Parity reported G P
		1. Prior Term Pregnancies (number or fill UNK if unknown)
		2. Prior Preterm Pregnancies (<37 wk) (number or fill UNK if
		unknown)
		3. Abortions/miscarriage (<20 wk) (number or fill UNK if unknown)
		4. Born Alive (number or fill UNK if unknown)
		GESTATIONAL AGE ASSESSMENT
4.	Recorded	gestational age (from chart)
		(Number: weeks/days, if absent or unknow state UNK)
5.	How was	reported gestational age above assessed (tick one, and if unknown tick other and
	state UNK	
		Antenatal Maternal US
		LMP
		Infant Exam,
		Other (describe)

6. Elements of GA available in the record. (tick one option on each line for
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		Recorded	NOT recorded	Incomplete/ uncertain	Comments/Issues
a.	Intrauterine insemination				
b.	Embryo transfer				
c.	Certain LMP (LMP known)				
d.	Uncertain LMP (LMP not known)				
e.	First trimester US				
f.	Second trimester US				
g.	Third trimester US				
h.	Fundal height (any)				
i.	Fundal height in 2 nd trimester				
j.	Maternal physical exam in 1 st trimester				
k.	Birth weight				
l.	Newborn GA by physical exam				

7.	Assessment of Gestational Age LOC based on GAIA Definition (Use Case Definition
	Checklist:see appendix 2):

a.	Level of certainty		(1,2,3,4,5 or UNK: unable to assess)
b.	If unable to assign GA	LOC, describe	the reason(s):
Re	ason		

FGR CASE DEFINITION SPECIFIC VARIABLES

	Parameter	Evider	ice in Mo	edical Record or S	Study record
		Yes*	No*	Uncertain/ not recorded	Comments
a.	Estimated fetal weight below 3% using locally accepted growth curve				
b.	Estimated fetal weight below 10% using locally accepted growth curve				
c.	Oligohydramnios ¹ present				
d.	Absent or reversed end-diastolic flow of the umbilical artery doppler				
	NO FINDINGS of absent or reversed end-diastolic flow of the umbilical artery or oligohydramnios means recorded evidence, No means evidence of absence				
	QUALITY ASSESSMENT C	ASE DE	FINITI	ON	
	QUALITY ASSESSMENT Consideration of LOC for FGR ppendix 1):				in
	ase abstractor's best assessment of LOC for FGR ppendix 1):	t is (Use	Case De		in
	ase abstractor's best assessment of LOC for FGR ppendix 1):	R is (Use	Case De	finition Checklist	in

(1X, 2X or UNK: unable to assess)

Final CRF FGR NVPO. Authors Eckert L, Munoz F, Sturkenboom M, Black S

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

a. Level of certainty

Reason _		 	
11. Other comm	ents:		

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 loally-accepted growth curve AND □ 3. Absent or reversed end-diastolic flow of the umbilical artery Dopper OR □ 3. Oligohydramnios¹
Level 1b of diagnostic certainty □ 1. Level 1 evidence of pregnancy dating (see gestational age algorithm) AND □ 2. Estimated fetal weight below 10% using loally-accepted growth curve AND □ 3. No findings of absent or reversed end-diastolic flow of the umbilical artery Dopper OR □ 3. No findings of oligohydramnios¹
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 loally-accepted growth curve AND □ 3. Absent or reversed end-diastolic flow of the umbilical artery Dopper OR □ 3. Oligohydramnios¹
Level 2b of diagnostic certainty □ 1. Level 2 evidence of pregnancy dating (see gestational age algorithm) AND

□ 2. Estimated fetal weight below 10% using loally-accepted growth curve AND
\lnot 3. No findings of absent or reversed end-diastolic flow of the umbilical artery Dopper
OR Control of the con
□ 3. No findings of oligohydramnios¹
OR Control of the con
□ 4. Level 1 evidence of pregnancy dating (see gestational age algorithm) AND
☐ 5. Estimated fetal weight below 10% using loally-accepted growth curve AND
□ 6. No findings of oligohydramnios AND
□ 7. Inability to assess umbilical arter Doppler

Insufficient evidence:

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

¹ 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

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 (< 13 6/7 weeks).
- 2nd trimester scan (14 0/7–27 6/7 weeks).
- 3rd trimester (280/7 + 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 < 14 weeks; within 14 days at <26 weeks; within 21 days beyond 26 weeks.

*Uncertain LMP – first trimester (<13 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 0/7–27 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
\Box 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 (< 13 6/7 weeks).
Level 2A
$\hfill \square$ 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
\square 2. Certain LMP* with 1st trimester physical examination.
Level 2B
\Box Uncertain LMP with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks).
Level 3A
\Box 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
\square 4. Uncertain LMP with 1st trimester physical examination.
Level 3B
□ 1. Uncertain LMP with FH.
OR
□ 2. Uncertain LMP with newborn physical assessment.
OR

 $\hfill \square$ 3. Uncertain LMP with Birth weight.