

**NVPO Definitions Project
DATA COLLECTION FORM v0.9_15Feb2018
NON REASSURING FETAL STATUS (NRF)**

ADMINISTRATIVE INFORMATION

Initials of person performing the review: __ __

Outcome code: NRF

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 NRF
Country Site Origin Number (starting with 01)

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

COMMON VARIABLES

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)

GESTATIONAL AGE ASSESSMENT

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 nd trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j. Maternal physical exam in 1 st 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 _____

CASE DEFINITION SPECIFIC VARIABLES

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 ¹	<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"/>	

QUALITY ASSESSMENT CASE DEFINITION

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:

¹NICHD Three-tier Fetal Heart Rate Interpretation System (2008)

FHR Designation	Description
Category I tracing	<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>
Category II tracing	<p>FHR tracing does not meet criteria for category I or category III</p>
Category III tracing	<p>1)<i>Variability:</i> Absent FHR baseline variability</p> <p>AND any of the following: Recurrent late decelerations Recurrent variable decelerations Bradycardia (FHR<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 ≤ 14 weeks; within 14 days at ≤ 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.

