NVPO Definitions Project
DATA COLLECTION FORM v1.0 (June 29, 2018)
MILD PRE-ECLAMPSIA (PIH)

ADMINISTRATIVE VARIABLES

Initials of person performing the review: __ __

Outcome code:　　　PIH

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　　**PIH**　　_____　　_____　　_____　　_____
　　　　　　　　　　　　　　　　Country　　**Site**　　　**Origin**　　　**Number (starting with 01)**

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

COMMON VARIABLES

---

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

    Vaccine ____

    Drug _____

    Epidemiologic _____

    Other _____

2. **Year of event:**　　_____　　　　　　(full year)

Final CRF PIH NVPO project: authors: Eckert L, Munoz M, Sturkenboom M, Black S

3. **General pregnancy variables**

    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: _____

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) _____

Final CRF PIH NVPO project: authors: Eckert L, Munoz M, Sturkenboom M, Black S

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

	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 2nd trimester**				_____
j. **Maternal physical exam in 1st 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):

   Reason _____

PIH CASE DEFINITION SPECIFIC VARIABLES

8. **Elements of the Mild Pre-Eclampsia definition in clinical or study Record (please tick one on each line)**

Parameter	Evidence in Medical Record or Study record			
	Yes*	**No***	**Uncertain**	**Comments**
a. **Ability to measure blood pressure**				
b. **Blood pressure noted before 20 weeks gestation**				
c. **Blood pressure noted after 20 weeks gestation**				
d. **Dip urine for protein**				
e. **12 or 24 hour urine for protein**				
f. **Spot protein:creatinine ratio**				
g. **Pregnancy > 20 weeks gestation**				
h. **New onset proteinuria diagnosed with >=1+ protein on urine dipstick**				
i. **New onset proteinuria diagnosed with>=300 mg protein on 24 hour urine collection**				
j. **Spot protein:creatinine ratio >=0.3**				
k. **New onset hypertension with documented prior normal BP**				
l. **Systolic blood pressure >= 140 mm HG and/or diastolic blood pressure >=90mm Hg) sustained on two measurements over a minimum of 1 hour**				
m. **Systolic blood pressure >= 140 mm HG and/or diastolic blood pressure >=90mm Hg) sustained on two measurements over a minimum of 1 hour**				

*Yes means recorded evidence, No means recorded evidence of absence

QUALITY ASSESSMENT PIH CASE DEFINITION

9. **Case abstractor's best assessment of LOC for Mild Pre-Eclampsia (Use Case Definition Checklist in appendix 1):**

    a. Level of certainty _____ (1,2, or UNK unable to assess)

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

    Reason _____

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

    a. Level of certainty _____ (1,2, or UNK unable to assess)

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

    Reason _____

11. **Other comments**

    _____

Appendix 1: Mild Pre-Eclampsia (PIH)
Guide for LOC assignment for PIH (check all that are present)

"Mild Pre-Eclampsia" (Mild PIH) has been defined as a clinical syndrome characterized by elevation of blood pressure after 20 weeks over baseline. The PIH working group decided that having a baseline blood pressure before 20 weeks, then one after twenty weeks, as well as having a way to measure protein in the urine were key elements of the definition.

Case definition of Mild Preeclampsia

Case definition of Mild Preeclampsia

For all LEVELS:
□ 1. Pregnancy >= 20 weeks gestation AND
□ 2. New onset hyptertension (systolic blood pressure >= 140 mm Hg OR
□ 2. New onset diastolic blood pressure >= 90 mm HG AND
□ 3. Blood pressure elevation sustained on two measurements over a minimum of 1 h AND
□ 4. New onset proteinurea

Level 1 of diagnostic certainty
□ 1. New onset proteinuria diagnosed with>=300 mg protein on 24 hour urine collection OR
□ 1. Spot protein:creatinine ratio >=0.3

Level 2 of diagnostic certainty
□ 1. New onset proteinuria diagnosed with >=1+ protein on urine dipstick

NO Level 3-5 definitions exist for Pre-Eclampsia (PIH)

Insufficient evidence:
□ 1. Blood pressure cannot be measured
□ 2. No proteinuria evaluation is available

Final CRF PIH NVPO project: authors: Eckert L, Munoz M, Sturkenboom M, Black S

Appendix 2:

Gestational Age Assessment Guide

<u>**Definitions of terms used:**</u>

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 (28 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 (<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

Final CRF PIH NVPO project: authors: Eckert L, Munoz M, Sturkenboom M, Black S

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.

Final CRF PIH NVPO project: authors: Eckert L, Munoz M, Sturkenboom M, Black S