Baseline Assessment Case Report Form

A. Demographic Data

1. Date of baseline visit: D D M M M Y Y Y Y

2. Age at randomization: ☐☐ Years

3. Race/Ethnicity (may choose more than one):

☐ White/Caucasian ☐ Black/African Heritage ☐ Indigenous
☐ Asian/South East Asian ☐ Hispanic/Latino ☐ Pacific Islander

4. Height and weight prior to this pregnancy (can be reported by the subject):

Pre-pregnancy weight: _____ ☐ kg ☐ lbs
Height: _____ ☐ cm ☐ feet/inches
Pre-pregnancy BMI: _____ (kg/m^2)
If pre-pregnancy weight unknown, use subject's reported weight in 1st trimester

5. Current maternal weight (can be reported by the subject): _____ ☐ kg ☐ lbs

6. Smoking history:

Smoked in the last year? ☐ Yes ☐ No

Average number of cigarettes per day during pregnancy? ☐☐

Average number of cigarettes per day in the 3 months prior to pregnancy? ☐☐

Previous smoker? ☐ Yes ☐ No

If yes, quit date: M M M Y Y Y Y

Number of cigarettes per day (average over year prior to quitting): ☐☐

B. Medical History

1. Has any related family members had a VTE?

☐ No ☐ First degree relative ☐ Second degree relative

2. Prior medical issues?

☐ **No prior medical issues** ☐ **Yes**, please check all that apply:

☐ Systemic lupus erythematosus (SLE, lupus) ☐ Sickle cell disease
☐ Inflammatory bowel disease ☐ Hypertension (prior to pregnancy)
☐ Type 1 diabetes (prior to pregnancy) ☐ Type 2 diabetes (prior to pregnancy)
☐ Known kidney disease: _____ ☐ Known cardiac disease: _____
☐ Asthma ☐ Other inflammatory or autoimmune disorders(s): _____

3.	**Previous history of superficial vein thrombosis?**	☐ Yes ☐ No
	If yes, confirmed by ultrasound?	☐ Yes ☐ No
	If yes, pregnancy or postpartum related?	☐ Yes ☐ No
	If yes, exogenous estrogen related?	☐ Yes ☐ No
4.	**Previous history of varicose veins?** *(soft, dilated, large superficial veins)*	☐ Yes ☐ No

C. Obstetrical History

1. Parity:

Number of pregnancies carried past 20 weeks gestation (including current pregnancy): ☐☐

2. Prior cesarean delivery (not including current pregnancy)? ☐ Yes ☐ No

3. Did the subject have any complications during <u>PRIOR pregnancies</u>?

☐ **No complications** ☐ **Yes <u>PRIOR</u> complications**, please check all that apply:

- ☐ Gestational hypertension
- ☐ Pre-eclampsia
  - Largest amount of proteinuria documented if known:
    - Urine protein / Cr ratio: _____ mg/mmol spot urine
    - **OR** 24-hour urine protein: _____ grams
- ☐ Eclampsia (seizures)
- ☐ HELLP syndrome
- ☐ Gestational diabetes
- ☐ Intrauterine growth restriction or small-for gestational age
- ☐ Placental abruption
- ☐ Intrapartum infection (e.g. chorioamnionitis)
- ☐ Postpartum infection

4. Did the subject have any prior pregnancy losses?

☐ Yes ☐ No

☐	<10 weeks gestation	Number of losses: ☐☐
☐	10-20 weeks gestation	Number of losses: ☐☐
☐	>20 weeks gestation	Number of losses: ☐☐
☐	Unknown timing	Number of losses: ☐☐

D. Current Pregnancy

1. Method of conception:

☐ Spontaneous ☐ Ovulation induction with medical therapy

☐ Intrauterine insemination ☐ In vitro fertilisation (IVF) or Intracytoplasmic sperm injection

2. Aspirin use in current pregnancy: ☐ Yes ☐ No

If yes, dose per day: _____ mg

Gestational age when aspirin started: ☐☐ weeks + ☐ days

Date of last dose: D D M M M Y Y Y Y

3. Immobilization in current pregnancy:

Any type of bedrest at any point during pregnancy? ☐ Yes ☐ No

If yes, total days immobilized during this pregnancy: ☐☐

Bedrest at home? ☐ Yes ☐ No

Hospitalized for bedrest? ☐ Yes ☐ No

Type of bedrest (choose all that apply):

☐ Strict bedrest (>90% of time, bathroom privileges)
☐ Modified bedrest (Limited walking, restricted activities)

Reason for bedrest: _____

Number of episodes of bedrest: ☐☐

Gestational age at **start** of bedrest closest to delivery: ☐☐ weeks + ☐ days

Gestational age at **end** of bedrest closest to delivery: ☐☐ weeks + ☐ days

E. Delivery Details

1. Date of admission for labor/delivery: D D M M M Y Y Y Y

2. Date of delivery of infant: D D M M M Y Y Y Y

3. Date and time of delivery of placenta (24 hr clock): D D M M M Y Y Y Y

H H M M

4. Gestational age at delivery: ☐☐ weeks + ☐ days

5. Singleton or multiple pregnancy: ☐ Single ☐ Multiple pregnancy

6. Type of Labor:

- ☐ Spontaneous labor
- ☐ Induction of labor, reason if known:_____
- ☐ No labor (e.g. scheduled cesarean delivery)

7. Mode of Delivery:

- ☐ Vaginal delivery
  - ☐ Unassisted vaginal delivery
  - ☐ Assisted vaginal delivery (forceps/vacuum)
- ☐ Manual removal of placenta following vaginal delivery
- ☐ Cesarean delivery
  - ☐ Scheduled/planned cesarean delivery
  - ☐ Unplanned or emergency cesarean delivery, reason if known:

_____

8. Was the placenta previa or abnormally invasive? ☐ Yes ☐ No

9. Did the subject receive neuraxial anesthesia? ☐ Yes ☐ No

10. Was the subject's active labor prolonged >24 hours? ☐ Yes ☐ No

11. Postpartum hemorrhage?

☐ Yes ☐ No ☐ Unknown

If yes, estimated blood loss: ☐☐☐☐ mL

Estimated blood loss measured by: ☐ Visual estimate

☐ Counting/weighing pads or bedding

12. Did the subject receive a red blood cell transfusion?

☐ Yes, number of units ☐☐ ☐ No

13. Did the subject have any complications during the <u>CURRENT</u> pregnancy?

☐ **No complications** ☐ **Yes CURRENT pregnancy complications ,** please check all that apply:

- ☐ Gestational hypertension
- ☐ Pre-eclampsia

  Largest amount of proteinuria documented:

  Urine protein / Cr ratio: _____ mg/mmol spot urine

  OR 24-hour urine protein: _____ grams
- ☐ Eclampsia (seizures)
- ☐ HELLP syndrome
- ☐ Gestational diabetes
- ☐ Intrauterine growth restriction or small-for gestational age
- ☐ Placental abruption
- ☐ Intrapartum infection (e.g. chorioamnionitis)
- ☐ Postpartum infection

14. Laboratory results:

Last known hemoglobin count: _____ g/L ☐ Pre-delivery ☐ Postpartum

Date of result: D D M M M Y Y Y Y

Last known platelet count: _____ x 10^9/L ☐ Pre-delivery ☐ Postpartum

Date of result: D D M M M Y Y Y Y

COVID-19 status in the last 14 days?

☐ Positive result ☐ Negative result

☐ Pending result ☐ Unknown result/Not done

Date of test: D D M M M Y Y Y Y

If **pending**, indicate final result: ☐ Positive ☐ Negative

F. Infant Details

1. Current pregnancy: Infant sex and weight:

Infant	Live birth (Y/N)	Sex (M/F)	Weight (g)
A			
B			
C			

G. Immediate Postpartum Details

1. Date and time of first mobilization after delivery (as reported by subject):

Date: D D M M M Y Y Y Y

Time (24 hr clock): H H M M

2. Use of pneumatic compression devices, graduated compression or TED stockings since delivery (can be reported by the subject)?

☐ **Yes,** please specify the type used: ☐ No

☐ Pneumatic compression device Number of hours used: | |

☐ Graduated compression stockings Number of hours used: | |

☐ TED stockings (<20 mmHg) Number of hours used: | |

3. Since delivery, has the subject received low-molecular-weight-heparin (LMWH) or unfractionated heparin (UFH)?

☐ **Yes,** please specify dose of LMWH or UFH: ☐ No

☐ Enoxaparin _____ mg ☐ Dalteparin _____ IU

☐ Tinzaparin _____ IU ☐ Nadroparin _____ IU/mg

☐ Unfractionated heparin _____ IU

Frequency of doses given: ☐ Q24H ☐ Q12H ☐ Q8H

Number of doses given since delivery: ☐ 1 ☐ 2

Date of last dose: D D M M M Y Y Y Y

Time of last dose: H H M M

4. Hospital discharge date: D D M M M Y Y Y Y

Delegate's Name

Delegate's Signature

D D M M M Y Y Y Y

Date