6 - MATERNAL OUTCOME & POSTPARTUM MANAGEMENT FORM

This form should be completed for **ALL WOMEN WHO HAVE CONSENTED TO PARTICIPATE IN THE WILL TRIAL**

(EVEN IF THEY WERE NOT RANDOMISED)

Section 1 - Woman's details

1.1 Woman's study number ☐☐☐☐	1.2 Last 4 digits of woman's NHS number N N N N
1.3 Woman's DOB *e.g. JAN2017* M M M Y Y Y Y	

Section 2 - Admission for birth or within 28 days after birth

2.1.Was the woman admitted to hospital EITHER for birth, or within 28 days after birth if she gave birth outside the hospital setting? *Please NOTE that for all **RANDOMISED** women the dates of all other admissions should be recorded on the Maternal & Fetal Surveillance form.*

◯ No
◯ Yes

If **yes**, record the date of admission to hospital during which she gave birth, or within 28 days after birth if she gave birth outside the hospital setting.

Date of admission D D M M M Y Y Y Y	Date of discharge D D M M M Y Y Y Y

Section 3 - Proteinuria (AFTER consent and BEFORE birth)

3.1. Did the woman develop proteinuria between consent and birth? *(diagnosed by one or more of the following: ≥2+ by dipstick, ≥30mg/mmol by spot protein:creatinine ratio, or ≥0.3g/d by 24hr urine collection)*

◯ No ◯ Yes

If **no**, please proceed to **Section 4**.

If **yes**, date of FIRST diagnosis: D D - M M M - Y Y Y Y

If **yes**, how was it diagnosed? (Please mark No or Yes to EACH question.)

3.2 Urinary dipstick testing before birth? ◯ No ◯ Yes

If **yes**, what was the highest dipstick proteinuria documented before birth? *Please mark ONE only.*
◯ Negative/Trace ◯ 1+ ◯ 2+ ◯ 3+ ◯ 4+

3.3. 24-hour urine collection before birth? ◯ No ◯ Yes

If **yes**, what was the maximum amount of protein found? ___ ___ . ___ g/d

3.4. Spot urinary protein:creatinine ratio before birth? ◯ No ◯ Yes

If **yes**, highest ratio reported in relevant units: mg/mmol (equivalent to g/mol) ___ ___ ___ . ___	mg/g (equivalent to µg/mg) ___ ___ ___ . ___

3.5 Spot urinary albumin:creatinine ratio before birth? ◯ No ◯ Yes

If **yes**, highest ratio reported in relevant units: mg/mmol (equivalent to g/mol) ___ ___ ___ . ___	mg/g (equivalent to µg/mg) ___ ___ ___ . ___

Section 4 - Maternal symptoms or signs of pre-eclampsia (AFTER consent until primary hospital discharge or 28 days postpartum, whichever is EARLIER)

Please tick ANY symptoms that occurred, then specify the timing (before or after birth) and date of first occurrence or diagnosis.

Symptom	If occurred *(tick ALL timing that applies)*	If occurred, date of FIRST diagnosis
4.1 **Headache** *(severe)* ◯ Yes ◯ No	◯ Before birth ◯ After birth	D D - M M M - Y Y Y Y
4.2 **Visual scotomata** *(persistent)* ◯ Yes ◯ No	◯ Before birth ◯ After birth	D D - M M M - Y Y Y Y

Item	Timing	Date
4.3 **Clonus** *(defined as 5 beats or more)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
4.4 **Right upper quadrant abdominal or epigastric pain** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
4.5 **Chest pain** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
4.6 **Dyspnoea** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y

Please confirm all the above have been considered and only those ticked apply and those not ticked have not occurred. ◯ No ◯ Yes

Section 5 - Abnormal laboratory tests (AFTER consent until primary hospital discharge or 28 days postpartum, whichever is EARLIER)

Please tick ANY abnormal laboratory results that occurred, then specify the timing (before or after birth) and date of first occurrence or diagnosis.

Item	Timing	Date
5.1 **Platelet count <50x10^9/L** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
5.2 **Platelet count 50 to 99x10^9/L** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
5.3 **Platelet count 100 to 149x10^9/L** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
5.4 **Disseminated intravascular coagulation** *(as documented in the notes)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
5.5 **Haemolysis** *(schistocytes on peripheral blood film)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y

5.6 **Elevated AST or ALT** *(>40IU/L)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
5.7 **Elevated serum creatinine of ≥90 micromol/L** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y

Please confirm all the above have been considered and only those ticked apply and those not ticked have not occurred. ◯ No ◯ Yes

Section 6 - Maternal complications (AFTER consent until either primary hospital discharge or 28 days postpartum, whichever is EARLIER)

Please tick ANY complications that occurred, then specify the timing (before or after birth) and the date of first occurrence or diagnosis.

6.1 **Maternal death** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of death D D - M M M - Y Y Y Y
6.2 **Severe hypertension** *(systolic BP≥160mmHg or diastolic BP≥110mmHg, measured twice at least 15 minutes apart)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before randomisation (if applicable) ◯ After randomisaton and before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
6.3 **Uncontrolled hypertension** *(hypertension requiring administration of 3 or more different parenteral [intravenous or intramuscular] antihypertensive agents within a 12 hour period)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y

6.4 **Glasgow Coma Score (GCS)<13** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
6.5 **Stroke** *(acute symptoms of focal brain injury that have lasted over 24 hours, with type [ischaemic or haemorrhagic] confirmed by neuroimaging)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
6.6 **Transient ischaemic attack** *(acute symptoms of focal brain injury that have lasted over 24 hours)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
6.7 **Eclampsia** *(the onset of convulsions in a woman with pre-eclampsia not attributable to other causes)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
6.8 **Blindness** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis D D - M M M - Y Y Y Y
If **yes**, please specify: ◯ Retinal detachment *(peeling away of the retina from its underlying layer of support tissue diagnosed by ophthalmological exam)* ◯ Cortical blindness *(loss of visual acuity in the presence of intact pupillary response to light)*		
6.9 **Inotropic support** *(use of vasopressors to keep sBP > 90 mm Hg or a MAP >70 mmHg)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST vasopressor use D D - M M M - Y Y Y Y
6.10 **Pulmonary oedema** *(excess fluid in the lungs diagnosed clinically with one/more of oxygen saturation < 95%, directive treatment (e.g., diuretic therapy), or x-ray confirmation)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

6.11 **Respiratory failure not due to Caesarean delivery** *(ventilation either by endotracheal tube or non-invasively, or need for > 50% oxygen for > 1 hour, none of which is due to Caesarean delivery)*
○ Yes ○ No

If occurred *(tick ALL timing that applies)*
○ Before birth ○ After birth

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

6.12 **SpO2 (oxygen saturation) <90%**
○ Yes ○ No

If occurred *(tick ALL timing that applies)*
○ Before birth ○ After birth

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

6.13 **Myocardial ischaemia or infarction** *(by characteristic ECG changes and markers of myocardial necrosis)*
○ Yes ○ No

If occurred *(tick ALL timing that applies)*
○ Before birth ○ After birth

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

6.14 **Hepatic dysfunction** *(INR>1.2 in the absence of DIC or treatment with warfarin, OR, in the presence of DIC or treatment with warfarin: either mixed hyperbilirubinemia >1.0 mg/dL (or >17 μM) or hypoglycaemia <45 mg/dL (<2.5 mM) in the absence of insulin)*
○ Yes ○ No

If occurred *(tick ALL timing that applies)*
○ Before birth ○ After birth

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

6.15 **Hepatic haematoma** *(presence of a blood collection under the hepatic capsule as confirmed by imaging or at laparotomy)*
○ Yes ○ No

If occurred *(tick ALL timing that applies)*
◯ Before birth ◯ After birth

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

6.16 **Hepatic rupture** *(separate from haematoma)*
◯ Yes ◯ No

If occurred *(tick ALL timing that applies)*
◯ Before birth ◯ After birth

If occurred, date of FIRST diagnosis:
D D - M M M - Y Y Y Y

(Please proceed to next page.)

6.17 **Acute kidney injury or dialysis** *(serum creatinine >150μM in the absence of a baseline serum creatinine/rise in serum creatinine ≥26μM within 48 hours/ >50% rise in serum creatinine within the past 7 days/urine output <0.5ml/kg/hr for >6hr)/new dialysis (of any type))* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis: D D - M M M - Y Y Y Y
6.18 **Transfusion** *(of any blood product)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST transfusion: D D - M M M - Y Y Y Y

6.19 **Placental abruption**
◯ Yes ◯ No

If **yes**, what was the basis of the definition? *Please select ALL that apply*
- ◯ Abdominal pain or uterine contractions of sudden onset with vaginal bleeding (other than show)
- ◯ Abdominal pain or uterine contractions of sudden onset with intrauterine fetal death
- ◯ Abdominal pain or uterine contractions of sudden onset with disseminated intravascular coagulation
- ◯ Retroplacental clot at the time of delivery
- ◯ Placental pathology demonstrating the presence of retroplacental clot
- ◯ Placental pathology with histological findings of a chronic abruption

Please confirm all the above have been considered and only those ticked apply and those not ticked have not occurred. ◯ No ◯ Yes

If **abdominal pain**, date of FIRST onset: D D - M M M - Y Y Y Y

6.20 **Postpartum haemorrhage (PPH)** *(perceived abnormal bleeding following delivery and either hypotension or medical/surgical intervention)* ◯ Yes ◯ No	If occurred, date of PPH: D D - M M M - Y Y Y Y

6.21 **Intensive therapy unit (ITU) admission** *(to receive advanced respiratory support alone or monitoring and support for two or more organ systems)*
◯ Yes
◯ No

If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST admission: D D - M M M - Y Y Y Y	If occurred, date of discharge: D D - M M M - Y Y Y Y

If **yes** to ITU admission,
Was this to receive advanced respiratory support? ◯ No ◯ Yes
Was this to receive support for two or more organ systems? ◯ No ◯ Yes

6.22 **Known or suspected infection** *(that resulted in administration of antibiotics)* ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis: D D - M M M - Y Y Y Y

If **yes** to known or suspected infection,

Did the woman have a respiratory rate of 22/min or more?	◯ No	◯ Yes
Did the woman have altered mentation?	◯ No	◯ Yes
Did the woman have a systolic BP of 100mmHg or lower?	◯ No	◯ Yes

6.23 **Other serious maternal complication** ◯ Yes ◯ No	If occurred *(tick ALL timing that applies)* ◯ Before birth ◯ After birth	If occurred, date of FIRST diagnosis: D D - M M M - Y Y Y Y

If **other serious maternal complication**, please specify:

Please confirm all the above have been considered and only those ticked apply and those not ticked have not occurred. ◯ No ◯ Yes

Section 7 - Maternal management (AFTER birth until primary hospital discharge or 28 days postpartum, whichever is earlier)

7.1 Did the woman receive any antihypertensive medication(s)? ◯ No ◯ Yes

If **yes**, please specify antihypertensive agent(s): *Please mark no or yes to EACH medication.*

Labetalol	◯ No	◯ Yes
Methyldopa	◯ No	◯ Yes
Nifedipine long-acting (LA)	◯ No	◯ Yes
Nifedipine modified-release (MR)	◯ No	◯ Yes
Other	◯ No	◯ Yes

If **other**, please specify ALL antihypertensive medication(s):

____

7.2 Did the woman receive magnesium sulphate? ◯ No ◯ Yes

7.3 Was the woman discharged HOME after birth? ◯ No ◯ Yes

If **yes**, please specify the date of woman's first discharge home after birth *(and then go to Section 8)* D D M M M Y Y Y Y

If **no**, was the woman transferred to another hospital? ◯ No *(then go to Section 8)* ◯ Yes

If **yes**, was the transfer prior to 28 days after birth? ◯ No *(then go to Section 8)* ◯ Yes

If **yes**, please obtain records from other hospital. This form should reflect maternal outcomes and care until primary discharge home from hospital or 28 days after birth, whichever was EARLIER.

NAME of hospital where she was transferred ______________________________

Date of transfer to that that hospital D D M M M Y Y Y Y

Date of discharge from that hospital D D M M M Y Y Y Y

Section 8 - Form completion details and details of PI (or his/her delegate)

NAME of person completing form: ______________________________

Date of form completion: *e.g., 01JAN1997* D D M M M Y Y Y Y

The site PI must sign off this form based on review of sections 5 and 6 and the primary case notes or relevant copies. The PI should be masked to the woman's allocated group.

Should the site PI have been involved in the care of the woman, his/her delegate must undertake sign-off.

Name of PI or his/her delegate: *If not PI, delegate must appear on Site Signature and Delegation Log.*

____

Password of PI or his/her delegate (as proxy for signature): *If not PI, delegate must appear on Site Signature and Delegation Log.*

____

Date of password entry by PI or his/her delegate: *e.g., 01JAN1997* D D M M M Y Y Y Y

Thank you. The form is now complete.