UNiTY Clinical Pregnancy Outcome CRF

Please complete this CRF for each clinical pregnancy. For multiple pregnancies please complete one CRF for each fetus.

Couple Trial ID: ☐☐☐☐ / ☐☐☐

[If "Number of fetuses" answered **>1**, on the POST TREATMENT CRF show "More than one fetus was present at the early pregnancy scan, which fetus does this CRF relate to?"]

More than one fetus was present at the early pregnancy scan, which fetus does this CRF relate to? *[Options available to be based on ""Number of fetuses" from the Post-treatment CRF; if 2 on CRF then only options for 1 and 2 shown etc.]*

○ 1   ○ 2   ○ 3

Section 1 - Pregnancy outcome

Pregnancy outcome *Tick one*   ○ Live birth   ○ Miscarriage   ○ Stillbirth   ○ Termination

Date of birth/outcome   D D - M M M - Y Y Y Y

[If "Pregnancy outcome" answered **Live birth**, show "Birth details" section AND "Baby" sub-section]

Section 2 - Birth details

Was the partner providing eggs admitted to hospital to give birth?   ○ Yes   ○ No

[If "Was the partner providing eggs admitted to hospital to give birth?" answered **Yes**, show "Date of admission for birth" AND "Date of discharge home"]

Date of admission for birth	Date of discharge home
D D - M M M - Y Y Y Y	D D - M M M - Y Y Y Y

Birthweight ___ ___ ___ ___ grams

Sex of baby *Tick one*   ○ Male   ○ Female

Baby's NHS number ☐☐☐☐☐☐☐☐☐☐

Onset of labour *Tick one*   ○ Spontaneous   ○ Induced   ○ No labour/Planned caesarean

Mode of birth *Tick one*
○ Unassisted vaginal   ○ Instrumental vaginal   ○ Elective caesarean section   ○ Emergency caesarean section   ○ Other

[If "Mode of birth" answered **Other**, show "Please provide details of other birth mode"]

Please provide details of other birth mode _____

Section 3 - Safety and complications

Maternal

Did any of the following antenatal complications occur?

Placenta praevia *Tick one*	○ Yes	○ No	○ Unknown
Antepartum haemorrhage *Tick one*	○ Yes	○ No	○ Unknown
Pregnancy-induced hypertension *Tick one*	○ Yes	○ No	○ Unknown
PET/Pre-eclampsia/HELLP *Tick one*	○ Yes	○ No	○ Unknown
Obstetric cholestasis *Tick one*	○ Yes	○ No	○ Unknown
Preterm pre-labour rupture of membranes *Tick one*	○ Yes	○ No	○ Unknown
Gestational diabetes *Tick one*	○ Yes	○ No	○ Unknown
Other significant complication *Tick one*	○ Yes	○ No	○ Unknown

[If "Other significant complication" answered **Yes**, show "Please provide details of other significant complication"]

Please provide details of other significant complication _____

Did any of the following intrapartum or post-partum complications occur?

Chorioamnionitis *Tick one*	○ Yes	○ No	○ Unknown
Intrauterine growth restriction *Tick one*	○ Yes	○ No	○ Unknown
Macrosomia *Tick one*	○ Yes	○ No	○ Unknown
Haemorrhage *Tick one*	○ Yes	○ No	○ Unknown
Infection *Tick one*	○ Yes	○ No	○ Unknown
Other significant complication *Tick one*	○ Yes	○ No	○ Unknown

[If "Other significant complication" answered **Yes**, show "Please provide details of other significant complication"]

Please provide details of other significant complication _____

Baby

Was an APGAR score available?	○ Yes	○ No

[If "Was an APGAR score available?" answered **Yes**, show "APGAR score at 1 minute" AND "APGAR score at 5 minutes" AND "APGAR score at 10 minutes"]

APGAR score at 1 minute	APGAR score at 5 minutes	APGAR score at 10 minutes
○ 1-6 ○ 7-10	○ 1-6 ○ 7-10	○ 1-6 ○ 7-10

Did the baby experience any of the following complications until primary hospital discharge (or 28 days after birth, whichever is earlier)?

Congenital abnormalities *Tick one*	○ Yes	○ No	○ Unknown

[If "Congenital abnormalities" answered **Yes**, show "Please specify the details of the congenital abnormalities"]

Please specify the details of the congenital abnormalities _____

Chromosomal abnormalities *Tick one*	○ Yes	○ No	○ Unknown
Admission to neonatal care unit *Tick one*	○ Yes	○ No	○ Unknown
Early infection (as assessed by treating clinician) *Tick one*	○ Yes	○ No	○ Unknown
Retinopathy of prematurity *Tick one*	○ Yes	○ No	○ Unknown
Necrotising enterocolitis *Tick one*	○ Yes	○ No	○ Unknown

Intraventricular haemorrhage *Tick one*	◯ Yes ◯ No ◯ Unknown

Respiratory distress syndrome *Tick one*	◯ Yes ◯ No ◯ Unknown

Ventilation or oxygen support *Tick one*	◯ Yes ◯ No ◯ Unknown

Other significant complication *Tick one*	◯ Yes ◯ No ◯ Unknown

[If "Other significant complication" answered **Yes**, show "Please provide details of other significant complication"]

Please provide details of other significant complication	_____

[If "Was the partner providing eggs admitted to hospital to give birth?" answered **No**, show "Was the baby admitted to hospital"]

Was the baby admitted to hospital?	◯ Yes ◯ No

[If "Was the baby admitted to hospital?" answered **Yes**, show "Date of admission for baby"]

Date of admission for baby	D D - M M M - Y Y Y Y

[If "Was the partner providing eggs admitted to hospital to give birth" answered **Yes** OR "Was the baby admitted to hospital?" answered **Yes**, show "Date of discharge for baby" __AND__ "Was there an ongoing serious health issue at the time of discharge?"]

Date of discharge for baby	D D - M M M - Y Y Y Y

Was there an ongoing serious health issue at the time of discharge?	◯ Yes ◯ No

[If "Was there an ongoing serious health issue at the time of discharge?" answered **Yes**, show "Please provide details of the ongoing serious health issue"]

Please provide details of the ongoing serious health issue	_____

Has the baby died?	◯ Yes ◯ No

[If "Has the baby died?" answered **Yes**, show "Date of death"]

Date of death	D D - M M M - Y Y Y Y

If the couple or baby experiences a related and unexpected serious adverse event within 60 days of the cycle outcome please complete a Serious Adverse Event Form within 24 hours. Refer to Protocol for reporting guidance.

Section 4 - Sign off

Must be completed by someone who has signed the Site Signature and Delegation Log

Name	Date	D D - M M M - Y Y Y Y