UNiTY Post-Treatment CRF

Please complete one CRF per cycle, including any partial and cancelled cycles, 8 weeks after treatment starts (defined as the first day of ovarian stimulation).

Couple Trial ID | | | | | / | | | | |

Which treatment cycle does this relate to? ◯ IUI cycle 1 ◯ IUI cycle 2 ◯ IUI cycle 3 ◯ IVF ◯ Non-trial treatment

[If "Which treatment cycle does this relate to?" answered **IUI cycle 1**, **IUI cycle 2**, **IUI cycle 3** or **IVF**, show "Post-treatment complications" Section]

Section 1 - Post-treatment complications

Please only enter complications occurring due to a trial treatment

[If "Which treatment cycle does this relate to?" is answered **IVF** show the following instructional text.]

Were the following complications experienced in the 60 days following FSH injection?

[If "Which treatment cycle does this relate to?" is answered **IUI cycle 1**, **IUI cycle 2**, **IUI cycle 3** show the following instructional text.]

Were the following complications experienced **For partial or cancelled IUI cycles** - in the 30 days following the first day of ovarian stimulation (e.g. Letrozole)? **For completed IUI cycles** - in the 30 days following date of insemination?

Ovarian Hyperstimulation Syndrome (OHSS) ◯ Yes ◯ No

[If "Ovarian hyperstimulation syndrome (OHSS)" answered **Yes**, show "How severe was it?"]

How severe was it? *Tick one* ◯ Mild ◯ Moderate ◯ Severe

Pelvic infection ◯ Yes ◯ No

Bleeding post oocyte retrieval *[only show for **IVF**]* ◯ Yes ◯ No

Other ◯ Yes ◯ No

[If "Other" answered **Yes**, show "Please provide details"]

Please provide details _____

Were any additional procedures necessary?

Blood transfusion ◯ Yes ◯ No

Laparoscopy/laparotomy ◯ Yes ◯ No

Other ◯ Yes ◯ No

[If "Other" answered **Yes** show "Please provide details"]

Please provide details _____

[If "Blood transfusion" answered **Yes** OR "Laparoscopy/laparotomy" answered **Yes** OR "Other" answered **Yes**, show the following instructional text]

Please consider whether a Serious Adverse Event needs to be reported.

[If "Ovarian Hyperstimulation Syndrome (OHSS)" OR "Pelvic infection" OR Bleeding post oocyte retrieval" OR "Other" answered **Yes** OR "Blood transfusion" OR Laparoscopy/laparotomy" OR "Other" answered **Yes** show "Did the participant require hospitalisation due to these complications?"]

Did the participant require hospitalisation due to these complications? ◯ Yes ◯ No

[If "Did the participant require hospitalisation due to these complications?" answered **Yes**, show the following instructional text AND "What was the highest level of care received?"]

Please complete a Serious Adverse Event Form.

What was the highest level of care received? *Tick one*

◯ ITU/HDU admission ◯ Standard ward admission ◯ A&E visit ◯ Outpatient review

[If "What was the highest level of care received?" answered **ITU/HDU admission** OR **Standard ward admission** OR **A&E visit**, show "Date of hospital admission" and "Date of hospital discharge"]

Date of hospital admission D D - M M M - Y Y Y Y

Date of hospital discharge D D - M M M - Y Y Y Y

If the participant 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 2 - Biochemical pregnancy

[If "Which treatment cycle does this relate to?" answered **Non-trial treatment**, go straight to "Biochemical pregnancy" Section]

Date of pregnancy test D D - M M M - Y Y Y Y

Pregnancy test result ◯ Pregnant ◯ Not pregnant ◯ Not clear

[If "Pregnancy test result" answered **Not clear**, show the questions "Date of subsequent pregnancy test" AND "Subsequent pregnancy test result"]

Date of subsequent pregnancy test D D - M M M - Y Y Y Y

Subsequent pregnancy test result ◯ Pregnant ◯ Not pregnant

[If "Pregnancy test result" answered **Pregnant** OR "Subsequent pregnancy test result" answered **Pregnant**, show "Clinical pregnancy confirmation scan" section]

Section 3 - Clinical pregnancy

Clinical pregnancy confirmation scan

Was an early pregnancy scan performed? ◯ Yes ◯ No

[If "Was an early pregnancy scan performed?" answered **No**, show the question "Why not?"]

Why not? ◯ Miscarried before scan date ◯ Other

[If "Why not?" answered **Other**, show "Please provide details"]

Please provide details _____

[If "Was an early pregnancy scan performed?" answered **Yes**, show the question "Date of early pregnancy scan" AND "Was there a viable fetus?"]

Date of early pregnancy scan D D - M M M - Y Y Y Y

Was there a viable intrauterine pregnancy? ◯ Yes ◯ No

[If "Was there a viable intrauterine pregnancy?" answered **Yes**, show "Number of fetuses" AND "Number of fetal heartbeats"]

Number of fetuses ___ Number of fetal heartbeats *[Max = number of fetuses]* ___

[If "Number of fetuses" minus "Number of fetal heartbeats" > 0, show "Scan result of non-viable fetus"]

Scan result of non-viable fetus *Tick one* ◯ Missed miscarriage ◯ Ectopic ◯ Other

[If "Scan result of non-viable fetus" answered **Other**, show "Please provide details"]

Please provide details _____

[If "Number of fetuses" minus "Number of fetal heartbeats" > 1, show "Scan result of 2nd non-viable fetus"]

Scan result of 2nd non-viable fetus *Tick one* ◯ Missed miscarriage ◯ Ectopic ◯ Other

[If "Scan result of 2nd non-viable fetus" answered **Other**, show "Please provide details"]

Please provide details _____

[If "Was there a viable intrauterine pregnancy?" answered **No** show "Scan result"]

Scan result *Tick all that apply* ◯ Missed miscarriage ◯ Ectopic ◯ Biochemical pregnancy ◯ Other

[If "Scan result " answered **Other**, show "Please provide details"]

Please provide details _____

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