

## UNITY IVF Treatment CRF

Please complete one CRF for the first cycle of IVF, including any partial or cancelled cycles.

Couple Trial ID

 / 

## Section 1 - Randomisation

[If couple was randomised to receive IUI, show "Has the couple had 3 unsuccessful attempts of IUI?"]

Has the couple had 3 attempts of IUI that have not resulted in biochemical pregnancy?

☐ Yes ☐ No

[If "If no, has the couple had 3 unsuccessful attempts of IUI?" answered **No**, show "If not, please explain why they are undergoing IVF treatment before proceeding with this CRF"]

If not, please explain why they are undergoing IVF treatment before proceeding with this CRF.

[If "If no, has the couple had 3 unsuccessful attempts of IUI?" answered **No**, show the following instructional text]

Please complete a protocol deviation form if the couple did not receive their randomised treatment allocation. If the couple has withdrawn from the trial then please complete a Change of Status form.

## Section 2 - Stimulation injections

First day of last period   D     D   -   M     M     M   -   Y     Y     Y     Y  

Date of first FSH injection   D     D   -   M     M     M   -   Y     Y     Y     Y  

## Medication

IVF stimulation cycle type

☐ Agonist ☐ Antagonist ☐ Other

[If "IVF stimulation cycle type" answered **Other**, show "If other, please provide details"]

If other, please provide details

## Early Complications

Was the cycle cancelled before a trigger injection was administered?

☐ Yes ☐ No

[If "Was the cycle cancelled before a trigger injection was administered" answered **Yes**, show "Please specify the reason for cycle cancellation" and "Are the couple entitled to an additional round of IVF?"]

Please specify the reason for cycle cancellation

Predicted OHSS/For safety

☐ Yes ☐ No

Failed stimulation or under response

☐ Yes ☐ No

Clinical error

☐ Yes ☐ No

Other

☐ Yes ☐ No

[If "Clinical error" answered **Yes**, show "Are the couple entitled to an additional round of IVF?" and the following instructional text]

Please complete a protocol deviation form if the cycle was cancelled due to clinical error.

Are the couple entitled to an additional round of IVF?

☐ Yes ☐ No

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

If other, please provide details

[If "Was the cycle cancelled before a trigger injection was administered" answered **No**, show "Egg collection" section]

## Section 3 - Egg collection

## Medication

Date of trigger injection      D     D   -   M     M     M   -   Y     Y     Y     Y  Type of trigger injection ☐ GnRH (Buserelin/other) ☐ HCG (Ovitrelle/other)

## Procedure details

Did the participant undergo egg collection? ☐ Yes ☐ No[If "Did the participant undergo egg collection?" answered **No**, show "If no, why not?"]If no, why not? ☐ Participant withdrawal ☐ Other[If "If no, why not?" answered **Participant withdrawal**, show the following instructional text]

Please complete a Change of Status form

[If "If no, why not?" answered **Other**, show "If other, please provide details"]

If other, please provide details \_\_\_\_\_

[If "Did the participant undergo egg collection?" answered **Yes**, show "Date of egg collection" AND "Route of egg collection" AND "Number of follicles collected" AND "Number of mature eggs collected"]Date of egg collection      D     D   -   M     M     M   -   Y     Y     Y     Y  Route of egg collection ☐ Transvaginal ☐ Laparoscopic ☐ TransabdominalNumber of follicles detected             Number of eggs collected             

Details of transfer and results are captured in the Laboratory CRF

Complications of treatment should be detailed in the Post-treatment CRF

## 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