

UNiTY IUI Treatment CRF

Please complete one CRF for each of the first 3 cycles of IUI, including any partial or cancelled cycles.

Couple Trial ID /

Which cycle of IUI does this CRF refer to?

☐ 1 ☐ 2 ☐ 3

Section 1 - Stimulation

First day of last period - -

Ovarian stimulation method

☐ Letrozole ☐ OtherDate ovarian stimulation was started - - [If "Ovarian stimulation method" is answered **Other**, show following instructional text **AND** "If other, please specify"]

Please complete a deviation form if letrozole was not used for stimulation

If other, please specify

Is the number of dominant follicles known?

☐ Yes ☐ No[If "Is the number of dominant follicles known?" answered **Yes**, show "Number of dominant follicles"]Number of dominant follicles

Section 2 - Trigger Injection

Was a trigger injection done?

☐ Yes ☐ No[If "Was a trigger injection done?" answered **No**, show "If no, why not?"]

If no, why not?

☐ Under response to medication☐ Over response/hyperstimulated☐ Participant withdrawal☐ Clinical error☐ Other[If "If no, why not?" is answered **Participant withdrawal**, show the following instructional text]

Please complete a Change of Status form

[If "If no, why not?" is answered **Clinical error**, show the question "Was the IUI procedure completed" and the following instructional text]

Please complete a Protocol Deviation form if there was a clinical error

[If "If no, why not?" is answered **Other**, show the question "If other, please specify"]If other, please specify [If "Was a trigger injection done?" answered **Yes**, show "Date of trigger injection"]Date of trigger injection - -

Procedure details

Was the IUI procedure completed?

☐ Yes ☐ No[If "Was the IUI procedure completed?" answered **Yes**, show "Date of insemination" AND "Was luteal support provided?"]Date of insemination - -

Was luteal support provided?

☐ Yes ☐ No[If "was luteal support provided?" answered **Yes** show "If yes, what type?"]If yes, what type? ☐ Vaginal pessary ☐ Rectal pessary ☐ Injection ☐ Combined injection and pessary[If "Was the IUI procedure completed?" answered **No**, show "Reason not completed" and "Are the couple entitled to an additional round of IUI?"]

Reason not completed

☐ Poor quality semen ☐ Failed to pass catheter ☐ Clinical error ☐ Other[If "If no, why not?" is answered **Clinical error**, show the question "Are the couple entitled to an additional round of IUI?" and the following instructional text]

Please complete a Protocol Deviation form if there was a clinical error

[If "Reason not completed?" answered **Other**, show "If other, please specify"]

If other, please specify _____

Are the couple entitled to an additional round of IUI?

☐ Yes ☐ No

Details of insemination sample are included in the Laboratory CRF

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

Section 3 - Sign off

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

Name

Date - -