

UNiTY Laboratory CRF

[If "Was the IUI procedure completed?" on IUI CRF answered **No**, do not show this form]

[If "Did the participant undergo egg collection?" on IVF CRF answered **No**, do not show this form]

Please complete one CRF for every IVF treatment cycle that has resulted in egg collection and/or every IUI treatment cycle resulting in insemination within the trial

Couple Trial ID /

Which treatment cycle does this CRF relate to?

☐ IUI cycle 1 ☐ IUI cycle 2 ☐ IUI cycle 3 ☐ IVF

Section 1 - Semen analysis

Raw sample

Date of production - -

Days of abstinence before providing sample

Time of production :

Time of analysis :

Ejaculate volume . ml

Ejaculate concentration . million/ml

Rapid progressive (a) %

Slow progressive (b) %

Non-progressive (c) %

Immotile (d) %

Prepared treatment sample

Volume of prepared sample . ml

Concentration of prepared sample . million/ml

Rapid progressive (a) %

Slow progressive (b) %

Non-progressive (c) %

Immotile (d) _____ %

Trial video preparation

Have videos of the sample been recorded?

☐ Yes ☐ No[If "Have videos of the sample been recorded?" answered **No**, show the following instructional text]

Please complete a protocol deviation form

Trial slide preparation

Have the slides been prepared?

☐ Yes ☐ No[If "Have the slides been prepared?" answered **No**, show the following instructional text]

Please complete a protocol deviation form

Section 2 - Treatment samples

IUI treatment

[If "Which treatment cycle does this CRF relate to?" answered **IUI cycle 1, 2 or 3**, show "Volume of sperm sample inseminated" AND "Total sperm count of inseminated sample" AND "Sign off" section]

Volume of sperm sample inseminated ____ . ____ ml

Total sperm count of inseminated sample ____ . ____ million

IVF treatment

[If "Which treatment cycle does this CRF relate to?" answered **IVF** show "Was the prepared treatment sample combined with the partner's eggs?"]

Was the prepared treatment sample combined with the partner's eggs?

☐ Yes ☐ No[If "Was the prepared treatment sample combined with the partner's eggs?" answered **Yes**, show "How were the eggs inseminated?" AND "Fertilisation concentration around the egg"]

How were the eggs inseminated?

☐ IVF ☐ ICSI[If "How were the eggs inseminated?" answered **IVF**, show "Fertilisation concentration around the egg"]

Fertilisation concentration around the egg ____ . ____ million

[If "How were the eggs inseminated?" answered **IVF**, show "Number of eggs inseminated" AND "Please add the results of fertilisation at day 1" AND "MII" AND "GV" AND "MI" AND "2PN" AND "MPN" AND "Other"]

Number of eggs inseminated [piped through from IVF Treatment CRF "How many eggs were collected?"] ____

Please add the results of fertilisation at day 1:

MII ____

GV ____

MI ____

2PN ____

MPN ____

Other ____

[If "Other" answered **>0**, show "Please give details"]

Please give details _____

[If "How were the eggs inseminated?" answered **IVF**, show "Was rescue ICSI performed?"]

Was rescue ICSI performed?

☐ Yes ☐ No[If "How were the eggs inseminated?" answered **ICSI**, OR "Was rescue ICSI performed?" answered **Yes** show following instructional text AND "Number of eggs collected" AND "Please add the results of oocyte denudation after egg collection" AND "MII" AND "GV" AND "MI" AND "Atretic" AND "Other" AND "Please add the results of fertilisation at day 1" AND "MII" AND "1PN" AND "2PN" AND "MPN" AND "Degenerate" AND "Other (including abnormal)"]

Please complete a protocol deviation form for this couple.

ICSI treatment

Number of eggs collected: [piped through from IVF Treatment CRF "How many eggs were collected?"] ____

Please add the results of oocyte denudation after egg collection:

MII ____

GV ____

MI ____

Attretic ____

Other ____

[If "Other" answered >0, show "Please give details"]

Please give details _____

Please add the results of fertilisation at day 1:

MII ____

1PN ____

2PN ____

MPN ____

Degenerate ____

Other (including abnormal) ____

[If "Other (including abnormal)" answered >0, show "Please give details"]

Please give details _____

[If "Was the prepared treatment sample combined with the partner's eggs?" answered Yes, show "Was a fresh embryo transfer performed?"]

Section 3 - Embryo transfer

Was a fresh embryo transfer performed?

☐ Yes ☐ No

[If "Was a fresh embryo transfer performed?" answered No, show "Please give the reason" AND "Is a frozen embryo transfer planned?" AND "Were any embryos frozen?"]

Please give the reason.

No suitable embryos

☐ Yes ☐ No

Risk of OHSS

☐ Yes ☐ No

PGS testing

☐ Yes ☐ No

Progesterone too high

☐ Yes ☐ No

Clinical preference

☐ Yes ☐ No

[If "Clinical preference" answered Yes, show "Please provide details of clinical preference"]

Please provide details of clinical preference _____

Patient preference

☐ Yes ☐ No

[If "Patient preference" answered Yes, show "Please provide details of patient preference"]

Please provide details of patient preference _____

Other

☐ Yes ☐ No

[If "Other" answered Yes, show "Please provide details of other reason"]

Please provide details of other reason

Is a frozen embryo transfer planned?

☐ Yes ☐ No[If "Was a fresh embryo transfer performed?" answered **Yes**, show "procedure details" section" **AND** "Were any embryos frozen?"]

Procedure details

Date of fresh embryo transfer D D - M M M - Y Y Y Y

Number of embryos transferred

☐ 1 ☐ 2[If "Number of embryos transferred" answered **2**, show the question "Please give a reason why 2 embryos were transferred"]

Please give a reason why 2 embryos were transferred _____

Were these embryos confirmed euploid by PGTA?

☐ Yes ☐ No[If "Is a frozen embryo transfer planned?" answered **Yes**, show "embryo freezing" section"]

Section 4 - Embryo freezing

Please complete the details below about the number of embryos subsequent to transfer that were suitable for freezing on each day (not a cumulative total)

Were any embryos frozen?

☐ Yes ☐ No[If "Were there any embryos frozen?" answered **Yes**, show "How many embryos were suitable for freezing on day 1, AND day 2, AND day 3, AND day 4 AND day 5, AND day 6, AND day 7?"]How many embryos were suitable for freezing on **Day 1**?

[If "How many embryos were suitable for freezing on Day 1?" is answered >0, show "Of those that were suitable for freezing on Day 1, how many embryos were frozen on Day 1?"]

Of those that were suitable for freezing on Day 1, how many embryos were frozen on **Day 1**? How many embryos were suitable for freezing on **Day 2**?

[If "How many embryos were suitable for freezing on Day 2?" is answered >0, show "Of those that were suitable for freezing on Day 2, how many embryos were frozen on Day 2?"]

Of those that were suitable for freezing on Day 2, how many embryos were frozen on **Day 2**? How many embryos were suitable for freezing on **Day 3**?

[If "How many embryos were suitable for freezing on Day 3?" is answered >0, show "Of those that were suitable for freezing on Day 3, how many embryos were frozen on Day 3?"]

Of those that were suitable for freezing on Day 3, how many embryos were frozen on **Day 3**? How many embryos were suitable for freezing on **Day 4**?

[If "How many embryos were suitable for freezing on Day 4?" is answered >0, show "Of those that were suitable for freezing on Day 4, how many embryos were frozen on Day 4?"]

Of those that were suitable for freezing on day 4, how many embryos were frozen on **Day 4**? How many embryos were suitable for freezing on **Day 5**?

[If "How many embryos were suitable for freezing on Day 5?" is answered >0, show "Of those that were suitable for freezing on Day 5, how many embryos were frozen on Day 5?"]

Of those that were suitable for freezing on day 5, how many embryos were frozen on **Day 5**? How many embryos were suitable for freezing on **Day 6**?

[If "How many embryos were suitable for freezing on Day 6?" is answered >0, show "Of those that were suitable for freezing on Day 6, how many embryos were frozen on Day 6?"]

Of those that were suitable for freezing on day 6, how many embryos were frozen on **Day 6**?

How many embryos were suitable for freezing on **Day 7**?

[If "How many embryos were suitable for freezing on Day 7?" is answered >0. show "Of those that were suitable for freezing on Day 7, how many embryos were frozen on Day 7?"]

Of those that were suitable for freezing on day 7, how many embryos were frozen on **Day 7**?

Section 5 - 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