

UNITY Randomisation CRF

Please complete one randomisation CRF per couple.

Couple Trial ID:

 /

Section 1 - Randomisation timing

Estimated start date of treatment - -

Do not randomise the couple if there is more than three months expected between randomisation and treatment starting (defined as first day of ovarian stimulation).

Are you happy to proceed to randomisation? *Tick one*☐ Yes ☐ No[If "Are you happy to proceed to randomisation?" answered **No**, show "If not, please provide details"]If not, please provide details [If "Are you happy to proceed to randomisation?" answered **Yes**, show "Pre-Randomisation confirmations" section]

Section 2 - Pre-randomisation confirmations

Is the couple still eligible as per the inclusion and exclusion criteria on the screening CRF? *Tick one*☐ Yes ☒ NoIs the partner providing eggs younger than 39 on the date of randomisation? *Tick one*☐ Yes ☒ No

[If "Is the partner providing eggs younger than 39 on the date of randomisation?" to be determined by system]

[If "Is the partner providing eggs younger than 39 on the date of randomisation?" is **No**, show following instructional text]

If the partner providing eggs is older than 39 on date of randomisation then the couple is no longer eligible for UNITY.

Have both partners completed UNITY consent forms and are still happy to be randomised? *Tick one*☐ Yes ☒ No

If either partner has signed a paper consent form, please upload the fully signed copy to REDCap before proceeding with randomisation

For couples who do not qualify for NHS funding, has the cost of IVF treatment been paid? *Tick one*☐ N/A ☐ Yes ☒ No[If "For couples who do not qualify for NHS funding, has the cost of IVF treatment been paid?" answered **No**, show following instructional text]

The cost of the first IVF treatment MUST be paid prior to randomisation

[If any of the questions in Section 2 are answered **No**, show following instructional text]

If any of the above questions have been answered No, the couple cannot be randomised to the trial.

Section 3 - Minimisation

The following minimisation details have been collected in the screening and baseline CRFs. Please check and if incorrect, return to the relevant form and update.

Ethnicity of partner providing eggs [piped from screening]

BMI of partner providing eggs [calculated by system]

Age of partner providing eggs [calculated by system]

Section 4 - Eligibility assessment sign off

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

Name of person confirming eligibility:

Date: - -

Section 5 - Randomisation

Date of randomisation: D D - M M M - Y Y Y Y

Randomised allocation

☐ IVF☐ IUI

Section 6 - Sign off

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

Name: _____

Date: D D - M M M - Y Y Y Y