UNiTY Baseline CRF

Please complete one baseline CRF per couple.

Couple Trial ID	☐☐☐☐ / ☐☐☐☐

Section 1 - Couple details

Partner providing eggs

NHS Number	☐☐☐ ☐☐☐ ☐☐☐☐

Date of birth	D D - M M M - Y Y Y Y

Please note the partner providing eggs needs to be <39 years old on the date of randomisation to be eligible for UNiTY.

It may take a over a year to complete 3 cycles of IUI and a cycle of IVF, and older couples may lose their NHS IVF funding eligibility.

Height ___.___ ___ m	Weight ___ ___ ___.___ kg	BMI *[Calculated by system]* ___ ___.___ kg/m^2

Please note the partner providing eggs needs to have a BMI >19.0 and <34.9 to be eligible for UNiTY.

Partner providing sperm

NHS Number	☐☐☐ ☐☐☐ ☐☐☐☐

Date of birth	D D - M M M - Y Y Y Y

Height ___.___ ___ m	Weight ___ ___ ___.___ kg	BMI *[Calculated by system]* ___ ___.___ kg/m^2

Section 2 - Pregnancy history

Partner providing eggs

How many pregnancies has the partner providing eggs had?	___ ___

[If "How many pregnancies has the partner providing eggs had?" is answered >0, show the following questions: Year of positive pregnancy test; Conceived with current partner?; Method of conception; Pregnancy outcome.]

Please add details of all previous pregnancies

Year of positive pregnancy test	☐☐☐☐

Conceived with current partner?	◯ Yes ◯ No

Method of conception	◯ Natural ◯ IUI ◯ IVF ◯ Other fertility treatment

Pregnancy outcome *Tick one*

◯ Biochemical pregnancy   ◯ Ectopic pregnancy   ◯ Molar pregnancy   ◯ Miscarriage

◯ Stillbirth   ◯ Termination   ◯ Live pre-term birth   ◯ Live full-term birth

[Repeat above set of 4 questions according to how many pregnancies the partner providing eggs had; **Max 10 sets**]

Partner providing sperm

How many pregnancies has the partner providing sperm conceived **with other partners?** __ __

[If "How many pregnancies has the partner providing sperm conceived with other partners?" is answered >0, show the following questions: Year of positive pregnancy test; Method of conception; Pregnancy outcome.]

Please add details of all previous pregnancies of other partners

Year of positive pregnancy test	☐☐☐☐

Method of conception	◯ Natural ◯ IUI ◯ IVF ◯ Other fertility treatment

Pregnancy outcome *Tick one*

◯ Biochemical pregnancy   ◯ Ectopic pregnancy   ◯ Molar pregnancy   ◯ Miscarriage

◯ Stillbirth   ◯ Termination   ◯ Live pre-term birth   ◯ Live full-term birth

[Repeat above set of 3 questions according to how many pregnancies the partner providing sperm had with other partners; **Max 10 sets**]

Section 3 - Fertility treatment history

How long has the couple been trying to conceive?	◯ <1 year ◯ 1-2 years ◯ 2-4 years ◯ 4-8 years ◯ >8 years
How many NHS-funded fresh cycles of IVF have the couple had together previously?	◯ 0 ◯ 1 ◯ 2 ◯ 3
How many self-funded fresh cycles of IVF have the couple had together previously?	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ >3
How many embryo transfer events (including frozen) have the couple had together previously? *Enter Zero if none.*	☐☐

Section 4 - Fertility investigations

Partner providing eggs

Type of menstrual cycle	◯ Regular ◯ Irregular ◯ Unknown

[If "Type of menstrual cycle" answered **Regular**, show "If regular, length of typical menstrual cycle"]

If regular, length of typical menstrual cycle __ __ days

Was FSH taken?	◯ Yes ◯ No

[If "Was FSH taken" answered **Yes**, show "Is the result of the FSH test available?"]

Is the result of the FSH test available?	◯ Yes ◯ No

[If "Is the result of the FSH test available?" answered **Yes**, show "If yes, date of test" <u>AND</u> "If yes, day in cycle" <u>AND</u> "FSH level"]

If yes, date of test	If yes, day in cycle __ __	FSH level __ __ . __ miU/l
D D - M M M - Y Y Y Y		

Was AMH taken?	◯ Yes ◯ No

[If "Was AMH taken?" answered **Yes**, show "If yes, date of test" <u>AND</u> "AMH level"]

If yes, date of test   D D - M M M - Y Y Y Y

AMH level __ __ __ . __ pmol/l

Was oestradiol taken?   ◯ Yes   ◯ No

[If "Was oestradiol taken?" answered **Yes**, show the questions "If yes, date of test" AND "If yes, day in cycle" AND "oestradiol level"]

If yes, date of test D D - M M M - Y Y Y Y	If yes, day in cycle __ __	Oestradiol level __ __ __ pmol/l

[If "Was AFC done?" answered **Yes**, show "If yes, date of test" AND "If yes, day in cycle" AND "AFC result"]

Was AFC taken?   ◯ Yes   ◯ No

If yes, date of test D D - M M M - Y Y Y Y	If yes, day in cycle __ __	AFC result __ __

Has the partner providing eggs had any pelvic surgery?   ◯ Yes   ◯ No

[If "Has the partner providing eggs had any pelvic surgery?" answered **Yes**, show "If yes, please specify", "Myomectomy", Endometrial surgery", Salpingectomy", Caesarean section", "Other"]

If yes, please specify

Myomectomy	◯ Yes ◯ No

Endometrial surgery	◯ Yes ◯ No

Salpingectomy	◯ Yes ◯ No

Caesarean section	◯ Yes ◯ No

Other	◯ Yes ◯ No

[If "Other" is answered **Yes**, show question "If other, please specify"]

If other please specify _____

Has the partner providing eggs had a tubal patency investigation?   ◯ Yes   ◯ No

[If "Has the partner providing eggs had a tubal patency investigation" answered **Yes**, show "If yes, date of test" AND "If yes, Left tube patency" AND "If yes, Right tube patency"]

If yes, date of test D D - M M M - Y Y Y Y	If yes, Left tube patency ◯ Yes ◯ No ◯ Other	If yes, Right tube patency ◯ Yes ◯ No ◯ Other

[If "If yes, left tube patency" answered **Other**, show "If left tube patency is answered other, please specify"]

If Left tube patency is answered other please specify _____

[If "If yes, right tube patency" answered **Other**, show "If right tube patency is answered other, please specify"]

If Right tube patency is answered other please specify _____

Partner providing sperm

Date of semen analysis   D D - M M M - Y Y Y Y

Days of abstinence before providing sample   __ __

Ejaculate volume __ __ . __ ml   Ejaculate concentration __ __ __ . __ million/ml

Was motility assessed?   ⚪ Yes - 4 part   ⚪ Yes - 3 part   ⚪ No

[If "Was motility assessed?" answered **Yes - 4 part**, show "Rapid progressive (a)" AND "Slow progressive (b)" AND "Non-progressive (c)" AND "Immotile (d)"]

[If "Was motility assessed?" answered **Yes - 3 part**, show "Progressive (a+b)" AND "Non-progressive (c)" AND "Immotile (d)"]

Rapid progressive (a)   __ __ __ %

Slow progressive (b)   __ __ __ %

Progressive (a+b)   __ __ __ %

Non-progressive (c)   __ __ __ %

Immotile (d)   __ __ __ %

Was 4 part morphology assessed?   ⚪ Yes   ⚪ No

[If "Was 4 part morphology assessed?" answered **Yes**, show "Head" AND "Midpiece" AND "Cytoplasmic droplet" AND and "Tail"]

Head   __ __ __ %

Midpiece   __ __ __ %

Cytoplasmic droplet   __ __ __ %

Tail   __ __ __ %

Was an overall morphology assessment performed?   ⚪ Yes   ⚪ No

[If "Was an overall morphology assessment performed?" answered **Yes**, show "Normal"]

Normal   __ __ __ %

Section 5 - General medical history

Partner providing eggs details

Current smoker	○ Yes	○ No

[If "Current smoker" answered **Yes**, show "If yes, how many cigarettes a day?"]

If yes, how many cigarettes a day?	___ ___

Alcohol	○ Yes	○ No

[If "Alcohol" answered **Yes**, show "If yes, how many units a week?"]

If yes, how many units a week?	___ ___

Recreational drugs	○ Yes	○ No

[If "Recreational drugs" answered **Yes**, show "If yes, name and frequency of use per month"]

If yes, name and frequency of use per month	

Does the partner providing eggs have any history of the following conditions?

Diabetes	○ Yes ○ No	Cardiac disease	○ Yes ○ No	Renal disease	○ Yes ○ No
Chronic hypertension	○ Yes ○ No	Thyroid disease	○ Yes ○ No	Autoimmune disorders	○ Yes ○ No
Inflammatory disorders	○ Yes ○ No	Cancer	○ Yes ○ No	Other	○ Yes ○ No

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

If other, please specify	

Partner providing sperm details

Current smoker	○ Yes	○ No

[If "Current smoker" answered **Yes**, show "If yes, how many cigarettes a day?"]

If yes, how many cigarettes a day?	___ ___

Alcohol	○ Yes	○ No

[If "Alcohol" answered **Yes**, show "If yes, how many units a week?"]

If yes, how many units a week?	___ ___

Recreational drugs	○ Yes	○ No

[If "Recreational drugs" answered **Yes**, show "If yes, name and frequency of use per month"]

If yes, name and frequency of use per month	

Does the partner providing sperm have any history of the following conditions?

Diabetes	○ Yes ○ No	Renal disease	○ Yes ○ No	Cardiac disease	○ Yes ○ No
Chronic hypertension	○ Yes ○ No	Thyroid disease	○ Yes ○ No	Autoimmune disorders	○ Yes ○ No
Inflammatory disorders	○ Yes ○ No	Cancer	○ Yes ○ No	Other	○ Yes ○ No

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

If other, please specify	

Section 6 - Relevant concomitant medications

Partner providing eggs details - prescribed medication

Is the partner providing eggs taking **regular** medication(s) for any of the following conditions? Please include both **prescribed and non-prescribed** medications. *Regular is defined as more than once per week*

Anxiety or depression	◯ Yes	◯ No
Asthma/lung function	◯ Yes	◯ No
Painkillers	◯ Yes	◯ No

Partner providing eggs details - supplements

Is the partner providing eggs taking any of the following supplements? If they are taking a combined supplement that contains multi-vitamins and folic acid, please answer YES to <u>BOTH</u> "multivitamins" and "folic acid".

Folic acid	◯ Yes	◯ No
Multivitamins	◯ Yes	◯ No
Other	◯ Yes	◯ No

[If "Multivitamins" answered **Yes** show "If multivitamins, please specify the brand/type"]

If multivitamins, please specify the brand/type	_____

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

If other, please specify	_____

Partner providing sperm details - prescribed medication

Is the partner providing sperm taking **regular** medication(s) for any of the following conditions? Please include both **prescribed and non-prescribed** medications. *Regular is defined as more than once per week*

Anxiety or depression	◯ Yes	◯ No
Asthma/lung function	◯ Yes	◯ No
Painkillers	◯ Yes	◯ No

Partner providing sperm details - supplements

Is the partner providing sperm taking any of the following supplements?.

Multivitamins	◯ Yes	◯ No

Other	◯ Yes ◯ No

[If "Multivitamins" answered **Yes** show "If multivitamins, please specify the brand/type"]

If multivitamins, please specify the brand/type _____

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

If other, please specify _____

Section 7 - NHS funding eligibility

What Integrated Care Board (ICB) is the couple's GP practice part of? *[List of ICBs (provided separately by Trial Team); autocomplete]*

_____

Does the couple qualify for NHS-funded IVF?	◯ Yes - through ICB ◯ Yes - through armed forces ◯ No

[If "Does the couple qualify for NHS-funded IVF?" answered **Yes - through ICB** <u>OR</u> **Yes - through armed forces**, show following instructional text]

Please communicate with couples any risk participation in the trial may have to their NHS IVF funding eligibility.

[If "Does the couple qualify for NHS-funded IVF?" answered **No**, show following instructional text]

If the couple are self-funding, they cannot proceed to randomisation until IVF payment has been received.

Has payment for one cycle of IVF been received by the clinic?	◯ Yes ◯ No

[If "Has payment for one cycle of IVF been received by the clinic?" answered **Yes**, show "Date of payment"]

Date of payment   D D - M M M - Y Y Y Y

Section 8 - 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