

UNiTY Screening CRF

Please complete one screening CRF per couple.

Couple Trial ID: *[assigned by system; first 4 digits = site HFEA number]* / Date of screening - -

Last 4 digits of NHS number of partner providing eggs

Last 4 digits of NHS number of partner providing sperm

Month and year of date of birth of partner providing eggs

 /

Section 1 - Eligibility checks

Has the couple completed all their fertility investigations? *Tick one*☐ Yes ☒ No*[If "Has the couple completed all their fertility investigations?" is answered No, show the following instructional text]*

If couple has not finished their investigations, please stop screening and resume when all the results are available.

[If "Has the couple completed all their fertility investigations?" is answered Yes, show "Inclusion criteria" section]

Section 2 - Inclusion criteria

Does the couple have a documented diagnosis of unexplained infertility? *Tick one*☐ Yes ☒ No

Unexplained infertility to be classed as **the ABSENCE of the following**: · **Partner providing eggs infertility due to**: Tubal disease; Deep endometriosis +/- ovarian endometriosis; Significant uterine abnormality requiring surgery (including cavity distorting fibroids, fibroids >5cm or multiple fibroids); Uterine septum with history of previous pregnancy loss. · **Partner providing sperm infertility due to**: Total progressively motile sperm count less than or equal to 10M; Normal sperm morphology of less than or equal to 2%.

[If "Does the couple have a diagnosis of unexplained infertility?" is answered No show "Does the partner providing sperm have normal sperm morphology less than or equal to 2%?"]

Does the partner providing sperm have normal sperm morphology less than or equal to 2%?

☐ Yes ☒ No*[If "Does the couple have a documented diagnosis of unexplained infertility?" is answered No, show the following instructional text]*

If the couple does not have a diagnosis of unexplained infertility they are not eligible for the UNiTY trial.

[If "Does the couple have a documented diagnosis of unexplained infertility?" is answered Yes, show "Exclusion criteria" section]

Section 3 - Exclusion criteria

Is the partner providing eggs 39 years or older on the date of randomisation, or if you are screening in advance, do you expect them to be 39 years or older on the date of randomisation?

☒ Yes ☐ No

Is either partner less than 18 years old on the date of consent?

☒ Yes ☐ NoDoes the partner providing eggs have a BMI < 19.0 or > 34.9kg/m²?☒ Yes ☐ No

Does either partner in the couple have a diagnosis of an ongoing sexually transmitted infection?

☒ Yes ☐ No

Is either partner taking any prohibited medication(s)/interventions(s)

☒ Yes ☐ No

Has the couple had two or more consecutive IVF treatment failures?

☒ Yes ☐ No

Is either partner unable to provide informed consent?

☒ Yes ☐ No

Is either partner unable to complete the trial follow-up?

☒ Yes ☐ No

If self-funded, is the couple unable to pay for IVF?

☒ Yes ☐ No ☐ N/A*[If any "Exclusion criteria" section question answered Yes, show the following instructional text]*

If yes to any of the above, the couple is not eligible for the UNiTY trial.

[If all "Exclusion criteria" section questions answered No or N/A, show "Further couple details for screening" section AND "Initial Discussion" section AND Qualitative research discussion" section]

Section 4 - Further couple details for screening

Partner providing eggs

Ethnicity *Tick one*

- ☐ Asian or Asian British
☐ Mixed or multiple ethnic groups

- ☐ Black, Black British, Caribbean or African
☐ Other ethnic group

[If "Ethnicity" answered **Asian or Asian British**, show "If Asian or Asian British - please specify"]

If Asian or Asian British - please specify *Tick one*

- | | |
|--|---------------------------------|
| <input type="radio"/> Bangladeshi | <input type="radio"/> Chinese |
| <input type="radio"/> Indian | <input type="radio"/> Pakistani |
| <input type="radio"/> Any other Asian background | |

[If "Ethnicity" answered **Black, Black British, Caribbean or African**, show "If Black, Black British, Caribbean or African - please specify"]

If Black, Black British, Caribbean or African - please specify *Tick one*

- | | |
|--|---------------------------------|
| <input type="radio"/> African | <input type="radio"/> Caribbean |
| <input type="radio"/> Any other Black, Black British or Caribbean background | |

[If "Ethnicity" answered **Mixed or multiple ethnic groups**, show "If Mixed or multiple ethnic groups - please specify"]

If Mixed or multiple ethnic groups - please specify *Tick one*

- | | |
|---|---|
| <input type="radio"/> White and Asian | <input type="radio"/> White and Black African |
| <input type="radio"/> White and Black Caribbean | <input type="radio"/> Any other Mixed or multiple ethnic background |

[If "Ethnicity" answered **Other ethnic group**, show "If Other ethnic group - please specify"]

If Other ethnic group - please specify *Tick one*

- | | |
|----------------------------|--|
| <input type="radio"/> Arab | <input type="radio"/> Any other ethnic group |
|----------------------------|--|

[If "Ethnicity" answered **White**, show "If White - please specify"]

If White - please specify *Tick one*

- | | |
|---|--|
| <input type="radio"/> English, Welsh, Scottish, Northern Irish or British | <input type="radio"/> Gypsy or Irish Traveller |
| <input type="radio"/> Irish | <input type="radio"/> Roma |
| <input type="radio"/> Any other White background | |

Does the partner providing eggs speak English as a first language? *Tick one*

☐ Yes ☐ No

[If "Does the partner providing eggs speak English as a first language?" answered **No**, show "If no, please provide the first language spoken" and "If no, are they fluent and confident in English to discuss the trial without the support of an interpreter?"]

If no, please provide the first language spoken _____

If no, are they fluent and confident in English to discuss the trial without the support of an interpreter? *Tick one*

☐ Yes ☐ No

Partner providing sperm

Ethnicity *Tick one*

- | | |
|---|--|
| <input type="radio"/> Asian or Asian British | <input type="radio"/> Black, Black British, Caribbean or African |
| <input type="radio"/> Mixed or multiple ethnic groups | <input type="radio"/> Other ethnic group |
| <input type="radio"/> White | |

[If "Ethnicity" answered **Asian or Asian British**, show "If Asian or Asian British - please specify"]

If Asian or Asian British - please specify *Tick one*

- | | |
|--|---------------------------------|
| <input type="radio"/> Bangladeshi | <input type="radio"/> Chinese |
| <input type="radio"/> Indian | <input type="radio"/> Pakistani |
| <input type="radio"/> Any other Asian background | |

[If "Ethnicity" answered **Black, Black British, Caribbean or African**, show "If Black, Black British, Caribbean or African - please specify"]

If Black, Black British, Caribbean or African - please specify *Tick one*

- | | |
|--|---------------------------------|
| <input type="radio"/> African | <input type="radio"/> Caribbean |
| <input type="radio"/> Any other Black, Black British or Caribbean background | |

[If "Ethnicity" answered **Mixed or multiple ethnic groups**, show "If Mixed or multiple ethnic groups - please specify"]

If Mixed or multiple ethnic groups - please specify *Tick one*

☐ White and Asian

☐ White and Black Caribbean

☐ White and Black African

☐ Any other Mixed or multiple ethnic background

[If "Ethnicity" answered **Other ethnic group**, show "If Other ethnic group - please specify"]

If Other ethnic group - please specify *Tick one*

☐ Arab

☐ Any other ethnic group

[If "Ethnicity" answered **White**, show "If White - please specify"]

If White - please specify *Tick one*

☐ English, Welsh, Scottish, Northern Irish or British

☐ Irish

☐ Any other White background

☐ Gypsy or Irish Traveller

☐ Roma

Does the partner providing sperm speak English as a first language? *Tick one*

☐ Yes ☐ No

[If "Does the partner providing sperm speak English as a first language?" answered **No**, show "If no, please provide the first language spoken" AND "If no, are they fluent and confident in English to discuss the trial without the support of an interpreter?"]

If no, please provide the first language spoken _____

If no, are they fluent and confident in English to discuss the trial without the support of an interpreter? *Tick one*

☐ Yes ☐ No

Section 5 - Initial discussion

Was the couple approached to discuss the UNiTY trial? *Tick one*

☐ Yes ☐ No

[If "Was the couple approached to discuss the UNiTY trial?" answered **No**, show "If no, please provide the reason"]

If no, please provide the reason *Tick the most accurate option*

☐ No research staff available

☐ Difficulties with arranging interpreters

☐ Staff felt that participation in the trial was not appropriate

☐ Other

[If "If no, please provide the reason" answered **Staff felt that participation in the trial was not appropriate**, show "If staff felt that participation in the trial was not appropriate, please provide details"]

If staff felt that participation in the trial was not appropriate, please provide details _____

[If "If no, please provide the reason" answered **Other**, show "If other, please provide details"]

If other, please provide details _____

[If "Was the couple approached to discuss the UNiTY trial?" answered **Yes**, show "Are the couple interested in taking part?"]

Are the couple interested in taking part?

☐ Yes ☐ No

[If "Are the couple interested in taking part?" answered **No**, show "If no, please provide the reason" AND "If no, who was against participating?"]

If no, please provide the reason *Tick all that apply*

☐ Did not want to be randomised

☐ Preference for IVF

☐

Were worried their NHS IVF funding eligibility would expire

☐ Other

☐ Did not want to be involved in research

☐ Did not want to take part in semen analysis

☐ Did not give a reason

[If "If no, please provide the reason" answered **Other**, show "If other please provide details"]

If other, please provide details _____

If no, who was against participating? *Tick one*

☐ Partner providing eggs ☐ Partner providing sperm ☐ Both

If "Are the couple interested in taking part?" answered **Yes**, show "How does the partner providing eggs prefer to complete the consent form and questionnaires?" **AND** "How does the partner providing sperm prefer to complete the consent form and questionnaires?"]

How does the partner providing eggs prefer to complete the consent form and questionnaires? *Tick one*

☐ Online via a link sent to their email ☐ Online via a link sent by text message
☐ Paper (with questionnaires via post)

If "How does the partner providing eggs prefer to complete the consent form and questionnaires?" answered **Online via a link sent to their email**, show "Add email address of partner providing eggs" **AND** "Add email address of person taking consent" **AND** "Does the partner providing eggs require an interpreter to help them consent?"]

If "How does the partner providing eggs prefer to complete the consent form and questionnaires?" answered **Online via a link sent by text message**, show "Add mobile phone number of partner providing eggs" **AND** "Add email address of person taking consent" **AND** "Does the partner providing eggs require an interpreter to help them consent?"]

Add email address of partner providing eggs:	<input type="text"/>
Add mobile phone number of partner providing eggs	<input type="text"/>
Add email address of person taking consent:	<input type="text"/>
Does the partner providing eggs require an interpreter to help them consent?	<input type="radio"/> Yes <input type="radio"/> No

If "Does the partner providing eggs require an interpreter to help them consent?" answered **Yes**, show "Add email address of interpreter"]

Add email address of interpreter:

If "How does the partner providing eggs prefer to complete the consent forms and questionnaires?" answered **Paper (with questionnaires via post)**, show following instructional text]

Couple can complete consent forms on paper now or the next time they attend clinic.

How does the partner providing sperm prefer to complete the consent form and questionnaires? *Tick one*

☐ Online via a link sent to their email ☐ Online via a link sent by text message
☐ Paper (with questionnaires via post)

If "How does the partner providing sperm prefer to complete the consent form and questionnaires?" answered **Online via a link sent to their email**, show "Add email address of partner providing eggs" **AND** "Add email address of person taking consent" **AND** "Does the partner providing sperm require an interpreter to help them consent?"]

If "How does the partner providing sperm prefer to complete the consent form and questionnaires?" answered **Online via a link sent by text message**, show "add mobile phone number of partner providing eggs" **AND** "Add email address of person taking consent" **AND** "Does the partner providing sperm require an interpreter to help them consent?"]

Add email address of partner providing sperm:	<input type="text"/>
Add mobile phone number of partner providing sperm	<input type="text"/>
Add email address of person taking consent:	<input type="text"/>
Does the partner providing sperm require an interpreter to help them consent?	<input type="radio"/> Yes <input type="radio"/> No

If "Does the partner providing sperm require an interpreter to help them consent?" answered **Yes**, show "Add email address of interpreter"]

Add email address of interpreter:

If "How does the partner providing sperm prefer to complete the consent forms and questionnaires?" answered **Paper (with questionnaires via post)**, show following instructional text]

Couple can complete consent forms on paper now or the next time they attend clinic.

Recruiter

Please enter the name of the clinician who approached this couple about the trial. *Must be on the delegation log*

Section 6 - Qualitative research discussion

Complete this section for ALL eligible couples during the pilot, regardless of whether they consented to the main UNITY trial.

Please explain that the UNITY qualitative researcher would like to talk to couples who have unexplained infertility and have been approached about taking part in the UNITY trial. We're interested in hearing their experiences whether they have agreed to be randomised, or declined, to take part in the trial. We're inviting couples (as individuals or together) to take part in a discussion (interview) with a researcher to talk about their thoughts on the trial, their reasons for taking part or not, and their views on the two different treatment options. Interviews will take about an hour and can done online or by phone on a date and time that suits them. Both patients will be offered a £25 shopping voucher for taking part. If they are interested in hearing more about the qualitative study, please support (one and/or both) them to complete the Section 6 Qualitative research discussion part of the screening form and tell them that a member of the qualitative research team will be in touch.

Please make it clear that they can change their mind and providing their details does not mean that they have to take part in an interview.

Was the qualitative process evaluation discussed with the couple? *Tick one*

☐ Yes ☐ No

[If "Was the qualitative process evaluation discussed with the couple?" answered No, AND "Are the couple interested in taking part?" answered No show the following instructional text]

If you were not able to discuss the qualitative process evaluation with the couple, and they were not interested in taking part in the UNITY trial, please send them the the QPE Follow-up Approach Declined Letter.

[If "Was the qualitative process evaluation discussed with the couple?" answered No, AND "Are the couple interested in taking part?" answered Yes show the following instructional text]

If you were not able to discuss the qualitative process evaluation with the couple, and they were interested in taking part in the UNITY trial, please send them the the QPE Follow-up Approach Accepted Letter.

[If "Was the qualitative process evaluation discussed with the couple?" answered Yes, show "Partner providing eggs" subsection AND Partner providing sperm" subsection]

Partner providing eggs

Has the partner providing eggs given permission to be contacted for more information by a member of the UNITY research team based at the University of Birmingham? *Tick one*

☐ Yes ☐ No

[If "Has the partner providing eggs given permission to be contacted for more information by a member of the UNITY research team based at the University of Birmingham?" answered Yes, show "If yes, how would they prefer to complete the consent to contact form?"]

If yes, how would they prefer to complete the consent to contact form? *Tick one*

☐ Online receiving link via email ☐ Online receiving link via text ☐ With researcher in clinic
☐ On paper

[If "If yes, how would they prefer to complete the consent to contact form?" answered Online receiving link via email, show "If online via an email, please enter their email" and instructional text]

If "online via an email", please enter their email: _____

A link to complete the Consent to Contact form will be sent to the above email address when this form is saved

[If "If yes, how would they prefer to complete the consent to contact form?" answered Online receiving link via text, show "If online via a text, please enter their mobile phone number" and instructional text]

If "online via a text", please enter their mobile phone number

A link to complete the Consent to Contact form will be sent to the above phone number when this form is saved

[If "If yes, how would they prefer to complete the consent to contact form?" answered With researcher in clinic, show following instructional text]

Please complete the Consent to Contact form on REDCAP

[If "If yes, how would they prefer to complete the consent to contact form?" answered On paper, show following instructional text AND "Has the partner providing eggs completed the Consent to Contact form on paper?"]

Please give the Consent to Contact form to the partner providing eggs for them to complete now or the next time they attend clinic.

Has the partner providing eggs completed the Consent to Contact form on paper?

☐ Yes ☐ No

[If "Has the partner providing eggs completed the Consent to Contact form on paper?" answered Yes, show following instructional text]

Please transcribe the details in to the Consent to Contact form

Partner providing sperm

Has the partner providing sperm given permission to be contacted for more information by a member of the UNITY research team based at the University of Birmingham? *Tick one*

☐ Yes ☐ No

[If "Has the partner providing sperm given permission to be contacted for more information by a member of the UNITY research team based at the University of Birmingham?" answered Yes, show "If yes, how would they prefer to complete the consent to contact form?"]

If yes, how would they prefer to complete the consent to contact form?

- ☐ Online receiving a link via an email ☐ Online receiving a link via a text ☐ With researcher in clinic
☐ On paper

[If "If yes, how would they prefer to complete the consent to contact form?" answered **Online receiving a link via an email**, show "If online via an email, please enter their email" and instructional text]

If "online via an email", please enter their email: _____

A link to complete the Consent to Contact form will be sent to the above email address when this form is saved

[If "If yes, how would they prefer to complete the consent to contact form?" answered **Online receiving a link via a text**, show "If online via a text, please enter their mobile phone number" and instructional text]

If "online via a text", please enter their mobile phone number

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[If "If yes, how would they prefer to complete the consent to contact form?" answered **With researcher in clinic**, show following instructional text **AND** contact details questions]

Please complete the Consent to Contact form on REDCAP

[If "If yes, how would they prefer to complete the consent to contact form?" answered **On paper**, show following instructional text **AND** "Has the partner providing sperm completed the Consent to Contact form on paper?"]

Please give the Consent to Contact form to the partner providing sperm for them to complete now or the next time they attend clinic.

Has the partner providing sperm completed the Consent to Contact form on paper?

☐ Yes ☐ No

[If "Has the partner providing sperm completed the Consent to Contact form on paper?" answered **Yes**, show following instructional text]

Please transcribe the details in to the Consent to Contact form

Section 7 - Sign off

Name _____

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