

UNITY Change of Status CRF

To be completed for all types of participant withdrawal in the UNITY trial. Couples who have decided not to adhere to their randomisation treatment allocation but are willing to be followed up in accordance with the schedule of assessments should not be treated as withdrawals, complete a protocol deviation form in this instance.

Section 1 - Participant Details

Couple Trial ID: /

Date of change of status: - -

Section 2 - Type of change of status

What type of status change is being reported? *If more than one type needs to be reported, please complete a separate form for each status change*

☐ **Death** Notification that one or both partners have died

☐

Partial withdrawal One or both partners wish to withdraw from certain aspects of the trial (intervention, follow-up, questionnaires and/or data collection)

☐

Complete withdrawal Only applicable to couples who have not yet started fertility treatment OR have completed fertility treatment. One or both partners wish to withdraw completely from the trial i.e. no further data will be collected

☐ **Loss to follow-up** It has not been possible to contact the couple despite repeated attempts

[If "What type of status change is being reported?" answered **Death, show "Section 3 - Death notification" AND "Section 10 - Sign off"]**

Section 3 - Death notification

Whose death is being reported? *Tick ALL that apply*

☐ Partner providing eggs ☐ Partner providing sperm

[If "Whose death is being reported?" answered **Partner providing eggs, show "Date of death of partner providing eggs" AND "Cause of death of partner providing eggs"]**

Date of death of partner providing eggs - -

Cause of death of partner providing eggs

[If "Whose death is being reported?" answered **Partner providing sperm, show "Date of death of partner providing sperm" AND "Cause of death of partner providing sperm"]**

Date of death of partner providing sperm - -

Cause of death of partner providing sperm

Please complete an SAE form

[If "What type of change of status is being reported?" answered **Partial withdrawal OR **Complete withdrawal**, show "Treatment continuation" AND "Reasons for change of status" AND "Sub-studies research - Qualitative Process Evaluation" AND "Sub-studies research - Bioethics study" AND "Sign off" sections]**

Section 4 - Treatment continuation

Have the couple discontinued fertility treatment? *Tick one* ☐ Yes ☐ No ☐ N/A - treatment already completed

[If "Have the couple discontinued fertility treatment?" answered **Yes**, show "Main reason why the couple discontinued fertility treatment" AND "Who requested fertility treatment be discontinued?"]

[If "Have the couple discontinued fertility treatment?" answered **No OR N/A - treatment already completed**, proceed to "Section 5 - Reasons for change of status"]

Main reason why the couple discontinued allocated treatment:

- ☐ Couple had a treatment related complication ☐ Couple wanted to proceed to IVF ☐ No reason given
☐ Other reason

[If "Main reason why the couple discontinued allocated treatment" answered **Couple had a treatment related complication**, show the following instructional text]

Please ensure that any treatment related complications are recorded in the relevant Post-treatment CRF

[hide option for "couple wanted to proceed to IVF" for couples allocated to IVF]

[If "Main reason why the couple discontinued allocated treatment" answered **Other reason**, show "If other reason, please specify"]

If other reason, please specify: _____

Who requested fertility treatment be discontinued? *Tick ALL that apply*

- ☐ Partner providing eggs ☐ Partner providing sperm ☐ Clinician ☐ Other person

[If "Who requested the fertility treatment be discontinued?" answered **Other person**, show "If other person, please state who"]

If other person, please state who: _____

[If "What type of change of status is being reported?" is answered **Complete withdrawal** AND "Have the couple discontinued fertility treatment?" is answered **Yes** show the following instructional text]

Categorisation: The couple have discontinued fertility treatment and have withdrawn from ALL trial follow-up activities. No further data will be collected (i.e., only data collected prior to withdrawal can be used in trial analysis).

[If "What type of change of status is being reported?" is answered **Complete withdrawal** AND "Have the couple discontinued fertility treatment?" is answered **No** show the following instructional text]

Categorisation: The couple continue to receive fertility treatment but would like to withdraw from ALL trial follow-up activities. No further data will be collected (i.e., only data collected prior to withdrawal can be used in trial analysis). This is considered a **partial withdrawal**, please change your response to "What type of status change is being reported?" to "Partial withdrawal".

[If "What type of change of status is being reported?" is answered **Complete withdrawal** AND "Have the couple discontinued fertility treatment?" is answered **N/A - treatment already completed** show the following instructional text]

Categorisation: The couple have already received fertility treatment and have now withdrawn from ALL trial follow-up activities. No further data will be collected (i.e., only data collected prior to withdrawal can be used in trial analysis).

Section 5 - Reasons for change of status

Please tick the reasons for change of status: *Tick ALL that apply*

- ☐ No reason given
☐ Couple no longer interested in research
☐ Couple changing address to area outside the catchment area of all trial sites
☐ Couple concerned over trial intervention
☐ Clinician concerned over trial intervention
☐ Couple have separated, or paused treatment due to relationship difficulties
☐ Couple no longer interested in fertility treatment
☐ Other reason

[If "Please tick the main reasons for the change of status" answered **Other reason**, show "If other reason, please specify"]

If other reason, please specify: _____

[If "What type of change of status is being reported?" answered **Partial withdrawal** show "Category of withdrawal section"]

Section 6 - Category of withdrawal

Partial withdrawal - No trial related follow-up: Are they withdrawing from attending trial visits in accordance with the schedule of assessments, but are willing to be followed up at standard clinic visits and, if applicable, using central UK NHS bodies for long-term outcomes (i.e., they have agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected as part of long-term outcomes)?

☐ Yes ☐ No

[If "Have the couple discontinued fertility treatment?" is answered **Yes** AND "Partial withdrawal - No trial related follow-up" is **Yes** show the following instructional text]

Categorisation: They have discontinued fertility treatment and have withdrawn from all trial related follow-up. They are willing to be followed up at standard clinic visits. Data collected will be used in the trial analysis, including data collected as part of long-term outcomes.

[If "Have the couple discontinued fertility treatment?" is answered **No OR N/A - treatment already completed** AND "Partial withdrawal - No trial

[If "Partial withdrawal - No trial related follow-up" is **No** show "Partial withdrawal - No follow-up questionnaire"]

Partial withdrawal - No follow-up questionnaires: Are the couple withdrawing from completing the patient questionnaires only?

☐ Yes ☐ No

[If "Have the couple discontinued fertility treatment?" is answered **Yes** AND "Partial withdrawal - No follow-up questionnaires" is **Yes** show the following instructional text]

Categorisation: They have discontinued fertility treatment and have withdrawn from completing trial questionnaires. The couple will continue to attend trial visits in accordance with the schedule of assessments and are willing to be followed up at standard clinic visits. Data collected will be used in the trial analysis, including data collected as part of long-term outcomes.

[If "Have the couple discontinued fertility treatment?" is answered **Yes** AND "Partial withdrawal - No follow-up questionnaires" is **No** show the following instructional text]

Categorisation: The couple have discontinued fertility treatment, but they will continue to attend trial visits in accordance with the schedule of assessments, **including** completing patient questionnaires and are willing to be followed up at standard clinic visits. Data collected will be used in the trial analysis, including data collected as part of long-term outcomes.

[If "Have the couple discontinued fertility treatment?" is answered **No** OR **N/A - treatment already completed** AND Partial withdrawal - No follow-up questionnaires" is **Yes** show the following instructional text]

Categorisation: The couple continue to receive/have already received fertility treatment, and they are still willing to attend trial visits. They are withdrawing from completing patient questionnaires. Data collected will be used in the trial analysis, including data collected as part of long-term outcomes.

[If "Have the couple discontinued fertility treatment?" is answered **No** OR **N/A - treatment already completed** AND Partial withdrawal - No follow-up questionnaires" is **No** show the following instructional text]

Categorisation: The couple continue to receive/are still receiving fertility treatment, and they are still willing to attend trial visits and complete patient questionnaires. Please reconsider whether a change of status is needed in this case. Please contact the trial office for advice.

[If "Have the couple stopped fertility treatment?" is answered **Yes** AND "Partial withdrawal - No trial related follow-up" is **Yes** show the following instructional text]

Categorisation: The couple is no longer receiving fertility treatment and have withdrawn from trial-related follow-up. They are willing to be followed up at standard clinic visits. Data collected will be used in the trial analysis, including data collected as part of long-term outcomes.

Section 7 - Sub-studies research - Qualitative Process Evaluation

Does the couple, or any partner within the couple, want to withdraw from the Qualitative Process Evaluation? *Tick ALL that apply*

☐ Yes - Partner providing eggs ☐ Yes - Partner providing sperm ☐ No ☐ N/A - did not consent initially

[If "Does the couple, or any partner within the couple, want to withdraw from the Qualitative Process Evaluation?" answered **Yes - Partner providing eggs** OR **Yes - Partner providing sperm** show the following instructional text]

Participants are free to withdraw within **2 weeks** of the data collection event - Please email the Qualitative Researchers immediately on **unityqualstudy@trials.bham.ac.uk**

Section 8 - Sub-studies research - Bioethics study

Does the couple, or any partner within the couple, want to withdraw from the Bioethics study? *Tick ALL that apply*

☐ Yes - Partner providing eggs ☐ Yes - Partner providing sperm ☐ No ☐ N/A - did not consent initially

[If "Does the couple, or any partner within the couple, want to withdraw from the Bioethics study?" answered **Yes - Partner providing eggs** OR **Yes - Partner providing sperm** show the following instructional text]

Participants are free to withdraw within **2 weeks** of the data collection event - Please email the Qualitative Researchers immediately on **unityqualstudy@trials.bham.ac.uk**

Section 9 - Sign off

[If "What type of change of status is being reported?" answered **Loss to follow-up**, proceed to "Section 9 -Sign off"]

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

Name: _____

Date - -