UNiTY Serious Adverse Event Form

Please complete for any serious, related and unexpected adverse events occurring within the protocol-defined reporting period - see section 10 for details. Please complete and upload to REDCap as soon as possible, and no later than 24 hours of becoming aware of the event.

[Up to and including "Sign off" section editable only by **Site PI** AND **Site Researcher** role]

Section 1 - Participant Details

Couple Trial ID: [ ][ ][ ][ ] / [ ][ ][ ][ ]

Who does this report relate to? *Tick one*

◯ Partner providing eggs ◯ Partner providing sperm ◯ Baby 1 ◯ Baby 2 (for multiple births) ◯ Baby 3 (for multiple births)

Is this an expedited SAE? *Tick one* ◯ Yes ◯ No

[If "Is this an expedited SAE?" is answered **No** show the following instructional text and do not allow to save the form.]

Only expedited SAEs should be reported on this form. Please refer to the protocol or contact the UNiTY trial office on unity@trials.bham.ac.uk for advice if you are unsure.

Section 2 - Details of Event

Date of onset: D D - M M M - Y Y Y Y

Date became serious: D D - M M M - Y Y Y Y

Date site became aware: D D - M M M - Y Y Y Y

What was the outcome of the event? ◯ Resolved without sequelae ◯ Resolved with sequelae ◯ Ongoing ◯ Fatal ◯ Unknown

[If "What was the outcome of the event?" answered **Resolved without sequelae** OR **Resolved with sequelae**, show "Date resolved"]

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

Section 3 - Event Information

Signs and symptoms: *include details of any concomitant events or medications that may have contributed to the event*

Diagnosis:

Event severity: *Tick one* ◯ Mild ◯ Moderate ◯ Severe

Section 4 - Seriousness of Event

Please answer each of the questions below:

Death: *Tick one* ◯ Yes ◯ No

[If "Death" is answered **Yes**, show "If yes, date of death" AND "If yes, cause of death"]

If yes, date of death: D D - M M M - Y Y Y Y

If yes, cause of death: _____

Life threatening event: *Tick one* ◯ Yes ◯ No

In-patient hospitalisation or prolongation of existing hospitalisation: *Tick one* ◯ Yes ◯ No

[If "In-patient hospitalisation or prolongation of existing hospitalisation" answered **Yes**, show "If yes, initial or prolonged?" AND "If yes, date of discharge"]

If yes, initial or prolonged? *Tick one* ◯ Initial ◯ Prolonged

If yes, date of discharge: D D - M M M - Y Y Y Y

Persistent or significant disability/incapacity: *Tick one* ◯ Yes ◯ No

Congenital anomaly or birth defect: *Tick one* ◯ Yes ◯ No

Other reason considered medically significant by the investigator: *Tick one* ◯ Yes ◯ No

[If "Other reason considered medically significant by the investigator" answered **Yes**, show "If other, please specify"]

If other, please specify:

Section 5 - Causality Assessment

Is the event related to the trial? *Tick one* ◯ Definitely ◯ Probably ◯ Possibly ◯ Unlikely ◯ Not related

Category	Definition	Causality
Definitely	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.	Related
Probably	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely.	
Possibly	There is some evidence to suggest a causal relationship. However, the influence of other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events or medication)	
Unlikely	There is little evidence to suggest there is a causal relationship. There is another reasonable explanation for the event (e.g., the participant's clinical condition, other concomitant events or medication).	Unrelated
Not related	There is no evidence of any causal relationship.	

[If "Is the event related to the trial" answered **Unlikely or Not related**, show "If the event is unrelated, please provide details of an alternative explanation for the event"]

If the event is unrelated, please provide details of an alternative explanation for the event:

Any investigations or lab tests that are considered relevant should be appended, please ensure any patient identifiers are redacted and replaced with trial ID

Section 6 - PI Review

Please confirm the SAE has been reviewed by the Principal Investigator or Medically Qualified Delegate *Tick one* ◯ Yes ◯ No

Name of reviewer

Role of reviewer

Date of review D D - M M M - Y Y Y Y

Section 7 - 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

Section 8 - CI/Delegate review

["CI/Delegate review" section editable only by users with **CI/Delegate** role]

CI/delegate review of relatedness *Tick one* ◯ Definitely ◯ Probably ◯ Possibly ◯ Unlikely ◯ Not related

Assessment of expectedness with reference to the protocol *Tick one* ◯ Expected ◯ Unexpected

BCTU comments

Name of person checking form

[If "CI/delegate review of relatedness" is answered **Definitely** OR **Probably** OR **Possibly**, AND "Assessment of expectedness with reference to the protocol" is answered **Unexpected** show the following instructional text AND "Date reported to REC" AND "Date reported to sponsor"]

If the event is related and unexpected - report to REC and sponsor

Date reported to REC D D - M M M - Y Y Y Y

Date reported to sponsor D D - M M M - Y Y Y Y

Name of BCTU staff member

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