[Form to be completed by each partner separately]

[When completed online, consent form to be preceded by **Patient Information Sheet**]

UNiTY Trial Couple Informed Consent Form

Please complete one form per individual

Couple Trial ID: | | | | | / | | | | |

Chief Investigator: Professor Jackson C Kirkman-Brown

Principal Investigator: [insert site PI name]

Please confirm your consent to take part in the UNiTY study by placing a tick in each box to indicate your agreement with the following statements:

I confirm that I have read and understand the patient information leaflet (version _._, dated _ _ / _ _ _ / _ _ _ _) for the UNiTY trial. I have had the opportunity to ask questions, and these have been answered satisfactorily. ☐

[Version number and date in statement "I confirm that I have read and understand the patient information leaflet ....." populated with **current** REC approved Patient Information Sheet details]

I understand that my participation in the trial is voluntary, and I am free to withdraw at any time without my treatment or legal rights being affected. ☐

I understand that a copy of my consent form, which identifies me by my name, and personal information about my progress, will be sent in confidence, to the study organisers at the University of Birmingham where my data will be stored for the UNiTY Trial. I agree to the transfer and storage of this data. ☐

I understand that all information collected on me, and my baby/babies (if applicable), for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018. This information will be stored securely at the University of Birmingham that is acting as the Data Controller for the UNiTY trial. I understand that I can withdraw my consent for the University of Birmingham to process the data about me at any time. ☐

I understand that all information collected on me, and my baby/babies (if applicable), will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that even if I withdraw from the study, information already collected about me and my baby/babies (if applicable) may be included in the final study analysis after being anonymised. ☐

I understand that relevant sections of my medical notes and those of my baby/babies if applicable (both paper and electronic) and data collected during the study may be looked at by individuals from the research team, representatives of the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research and any future related follow-on studies. I give permission for these individuals to have direct access to my records. ☐

[If completed by Partner providing sperm, show "**Partner providing sperm only:** I understand that videos..."]

Partner providing sperm only: I understand that videos of my sperm sample and fixed (dead) sperm surplus to our treatment will be taken and used for quality control to investigate male diagnosis in unexplained infertility. ☐

I understand that the information held by my fertility treatment centre may be used to keep in touch with me and follow up my status for the purposes of the study. ☐

I understand that researchers for the UNiTY Trial based at my hospital or at the University of Birmingham may contact me by telephone, mobile telephone, post or e-mail to request information. Where this relates to unexplained infertility related studies, my updated contact details may be traced through NHS databases and GP records. ☐

I understand that my General Practitioner will be informed about my participation in this trial. ☐

I understand the information that I have been given about the UNiTY trial and I agree to take part. ☐

Participant details:

First name of participant:	Last name of participant:
Signature of participant:	Date: D D - M M M - Y Y Y Y

Details of person taking consent:

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

First name:	Last name:
Signature:	Date: D D - M M M - Y Y Y Y

Was an interpreter used? ◯ Yes ◯ No

[If "Was an interpreter used?" answered **Yes**, show "Email of interpreter" AND "If yes, has the interpreter used patient information in the participant's first language?" AND "Interpreter details" sub-section]

If yes, has the interpreter used patient information in the participant's first language?

◯ Yes ◯ No ◯ Package not available in the participant's first language

Interpreter details (if applicable):

For the interpreter: *I confirm that I have interpreted the study information to the best of my ability and ensured the patient fully understands everything that has been given to them to read/verbally explained to them*

First name of interpreter:	Last name of interpreter:
Date: D D - M M M - Y Y Y Y	Signature of interpreter:

UNiTY Trial IRAS 314070

Master copy at University of Birmingham, 1 copy for the site file, 1 copy for participant notes and 1 copy for participant