**Pregnancy on A Clinical Study – Follow-up Form**

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| * Pregnancy on a Clinical Research Study must be recorded and reported to the Sponsor (Pharmacovigilance monitor). * It is desirable to follow-up the pregnancy but the mother’s consent must be obtained. * Please email this form to the [rde-tr.RandDSafetyReporting@nhs](mailto:rde-tr.RandDSafetyReporting@nhs) Safety Reporting mailbox within 24hrs of notification of the event. * Please use in connection with [S22 Safety Reporting](https://rderesearch.co.uk/about/standard-operating-procedures/) and [WI22  [Clinical Trial Participants & Pregnancy](https://rderesearch.co.uk/work-instructions/)](https://rderesearch.co.uk/work-instructions/). * This should follow the Pregnancy Notification Form, [FRM46](https://rderesearch.co.uk/templates-forms/). |

For subsequent follow-up reporting of a pregnancy, a new pregnancy follow-up reporting form should be completed with administrative details and all new or missing information, and forwarded to the R&D as soon as possible. All pregnancies must be followed-up until after birth.

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| **Study Details** | | | |
| **Study Title** |  | | |
| **Sponsor** |  | **Chief Investigator** |  |
| **Site** |  | **Principal Investigator** |  |
| **R&D Number** |  | **REC Number** |  |

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| **Participant Details** ***(Any information regarding female partners of male study participants should be entered in Other Pregnancy Information)*** | | | | | | |
| **Participant Initials** |  | | **Participant Study ID** | |  | |
| **Gender** | Male | Female | **Date of Birth** | | DD/MM/YYYY | |
|  | | | | | | |
| **Has CI been informed?** | Yes | No | **Was Study Unblinded?** | | Yes | No |
| **Has the mother given consent to follow up the pregnancy?** | | | Yes | No | | |
| **Has this been recorded in the participant’s EPIC record/notes?** | | | Yes | No | | |

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| **Prenatal Information *(tests and results)*** | | | | |
| **TEST** | | **DATE** | **Week of Pregnancy** | **Outcome** |
| **Urine** | Yes  No | DD/MM/YYYY |  |  |
| **Blood** | Yes  No | DD/MM/YYYY |  |  |
| **Ultrasound scan** | Yes  No | DD/MM/YYYY |  |  |
| **Amniocentesis** | Yes  No | DD/MM/YYYY |  |  |
| **Maternal serum AFP** | Yes  No | DD/MM/YYYY |  |  |
| **Chorionic Villus Sampling (CVS)** | Yes  No | DD/MM/YYYY |  |  |
| **Percutaneous Umbilical Blood Sampling (PUBS)** | Yes  No | DD/MM/YYYY |  |  |
| **Other** | Yes  No | DD/MM/YYYY |  |  |

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| **Pregnancy Outcome** | | | | | | |
| **Carried to term** | Yes  No  Not known at this time | | | | | |
| **If YES, please complete the delivery information below** | | | | | | |
| **Date of Delivery** | **Gestation (weeks)** | **Mode of delivery** | | | **Antenatal Problems** | **Postnatal Problems** |
| DD/MM/YYYY |  | Normal  Forceps/Ventouse  Caesarean | | |  |  |
| **If NO, please complete the section below** | | | | | | |
| **Induced abortion** | **Spontaneous abortion** | | **Still birth** | **Neonatal death** | | |
| **Birth defects (provide details in Other Pregnancy Information section below)** | | | **Date of above outcome** | | DD/MM/YYYY | |

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| **Child Outcome** | | | | | | | |
| **Gender** | **M  F** | **Weight (kgs)** |  | **Head Circumference (cm)** |  | **Length (cm)** |  |
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| **Apgar Scores** |  | **1 min** |  | **5 min** |  | **10 min** |  |

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| **Other Pregnancy Information (concurrent conditions, medical history, information regarding female partners of male study participants etc)** |
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| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR & CI (for Trust sponsored studies)** | | | | | |
| * Fill in the form, and email an electronic copy of the report to: [rde-tr.RandDSafetyReporting@nhs](mailto:rde-tr.RandDSafetyReporting@nhs).net * File the report form in the ISF/TMF in the Pharmacovigilance section * File a copy of the report in the Participant’s EPIC record/notes.   **NOTE –** If this follow-up form is being used for a Hosted Study where no pregnancy reporting procedures have been described remember to update R&D when you update the Sponsor. | | | | | |
| **Name of Investigator (for hosted studies)** |  | **Signature** |  | **Date** | DD/MM/YYYY |
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| **Name of CI** |  | **Signature** |  | **Date** | DD/MM/YYYY |

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| **For Sponsor / R&D Office Use only** | | | |
| **Date event reported** | **DD/MM/YYYY** | **Date event reviewed** | **DD/MM/YYYY** |
| **Has the event been reported as a safety event (AE/SAE/SUSAR)?** | **Yes  No** | **If yes, please record the DTX number:** |  |
| **Comments:** | |  | |