**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 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/).
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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 |
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| **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.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 |
|  |  |  |  |  |  |
| **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:** |  |