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| **PREGNANCY ON A CLINICAL TRIAL – FOLLOW UP FORM** |
| Pregnancy on a clinical trial ***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.  The forms are complementary to reduce duplication. This should follow the **Notification** form |

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| **1 – Trial Information** | |
| 1a) Sponsor |  |
| 1b) Chief Investigator |  |
| 1c) Investigator name (if other site) |  |
| 1d) Study site name |  |
| 1e) EudraCT number |  |
| 1f) R&D number |  |
| 1g) Study Title |  |

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| **2 – Participant information** | | | | |
| The participant is a **female** who became pregnant while taking part in a clinical trial. (tick if applicable) | | | |  |
| The participant is a **male** whose partner became pregnant while **he** was on a clinical trial. (tick if applicable) | | | |  |
| Has the mother given consent to follow up the pregnancy? | yes |  | no |  |

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| **3 - Maternal information** | | | | | | | | |
| **Initials** | **ID No** (if applicable) | | **DOB** | | **Last menses** | | **Expected delivery date** | |
|  |  | |  | |  | |  | |
| **If participant is male** | **Initials** |  | | **ID No** |  | **DOB** | |  |

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| **4 - Pre-Natal information (any tests performed and results)** | | | | | | |
| **Amniocentesis** | yes |  | no |  | Result |  |
| **Ultrasound** | yes |  | no |  | Result |  |
| **Maternal serum AFP** | yes |  | no |  | Result |  |
| **Other** |  | | | | | |

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| **5 - Pregnancy Outcome** | | | | | | | | | | | |
| Carried to term | yes |  | no |  | Week of delivery | | |  | | Date of delivery |  |
| If YES was the delivery | Normal | | |  | Forceps/Ventouse | | | |  | Caesarian |  |
| If NO was the termination | Spontaneous | | |  | Planned |  | Therapeutic | |  | Termination date |  |

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| **6 - Child Outcome** | | | | | | | | | | | | | | | | | | | | |
| Describe the birth | | | | | Normal | | | |  | | Abnormal\* | | | | |  | Stillbirth | | |  |
| Sex | male |  | female |  | Length | |  | | | Weight | | |  | Head circumference | | | | |  | |
| Apgar scores | | | 1 min | | |  | | 5 min | | | |  | | | 10 min | | |  | | |
| \**If ‘Abnormal’ give details.* | | | | | | | | | | | | | | | | | | | | |

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| **7 – Additional Information** |
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| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR** | | | | | |
| * Fill in the form and email an electronic copy to: tay.pharmacovigilance@nhs.scot * Put a signed copy in your Trial Master File in the Pharmacovigilance section * Receipt will be acknowledged by email | | | | | |
| Name of Investigator (If reporting from a participating site) |  | | | | |
| Signature |  | | Date | |  |
| Name of Chief Investigator. |  | | | | |
| Signature |  | Date | |  | |