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| **PREGNANCY ON A CLINICAL TRIAL – NOTIFICATION 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. The Follow up form should be used to complete the event. |

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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 ***female*** and has become pregnant while taking part in a clinical trial. (tick if applicable) | | | |  |
| The participant is ***male*** whose female partner has become pregnant while ***he*** is on a 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** | |
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| **If participant is male** | **Initials** |  | | **ID No** |  | **DOB** | |  |

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| **4 - Contraception** | | | | | | |
| Method (or none) |  | Used as instructed? | Yes |  | No |  |

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| **5 – Previous obstetric history**  (please continue in section 8 if required) | |
| **1** |  |
| **2** |  |
| **3** |  |

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| **6 – Relevant Medical History** |
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| **7 – Medication information** | | | | | | |
| **7a) Information about the IMP** | | | | | | |
| Drug | | Dose | Route | Start date | Stop date | Week of pregnancy when medication stopped |
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| **7b) Concomitant Medication at time of conception** | | | | | | |
| Drug | Indication | Dose | Route | Start date | Stop date | Action taken |
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| **8) Additional information** |
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| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR** | | | | |
| * Fill in the form andemail an electronic copy to: tay.pharmacovigilance@nhs.scot * Put one 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 | |  |