**PREGNANCY REPORTING FORM – CTIMPs**

* Send completed, signed Pregnancy Reporting Form to **UCL Joint Research Office within 24hrs of site awareness of the pregnancy:**

Email: **sae@ucl.ac.uk** or fax: **020 3108 2312**

* Please complete all sections, and enter dates as DD-MMM-YYYY,*i.e. 08-JUN-2018***.**
* For follow-up reports please initial and date all changes made, or complete a new Pregnancy Reporting Form with the updated information. Send to the JRO within 24hrs of site awareness of the new information. The Investigator must re-sign and date the follow-up report.
* Redact all patient identifiable data from any supporting documentation sent to the JRO.
* The Pregnancy Reporting Form should be filed in the Trial Master File / Investigator Site File, along with any relevant correspondence.

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| **Study Sponsor Number:**  | **Study Name:**  |

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| **Reporter Information** |
| **Reporter Name:** |       |
| **Email:** |       |
| **Phone number:** |       |
| **Job title:** |       |
| **Site:** |       |

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| **Report Details** |
| **Type of Report:**  | [ ]  Initial  | **Date site was first made aware of pregnancy**: |       |
| [ ]  Follow-up If follow-up, add follow-up #: |       | **Date this report was completed:** |       |

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| **Subject Information** |
| **Subject Trial ID:**  |       | **Pregnancy Report relates to:**  | [ ]  Trial subject [ ]  Trial subject’s partner |

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| **Investigational Medicinal Product (IMP) Information**  |
| **IMP(s)** **subject was receiving** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End date** |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
| Date of last dose of IMP prior to Pregnancy confirmation: |       | [ ]  | IMP not started (subject in screening) | Was study drug unblinded? *If applicable* | [ ]  Y [ ]  N |

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| **Non-Investigational Medicinal Product(s) (nIMP(s))** *if applicable* |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End Date** |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |

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| **Concomitant Medication** |
| **Any concomitant medication taken by the trial subject in the 30 days prior to pregnancy confirmation?** | [ ]  Yes [ ]  No *(if yes, provide details below and continue on a separate sheet if necessary)* |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End date** |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |

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| **Pregnancy Information** |
| **Start date of last menses:** |       | **Date pregnancy confirmed:** |       | **Method of diagnosis:** |       | **Mother consented for pregnancy monitoring:** | [ ]  Y [ ]  N [ ]  Pending |

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| **Pregnancy Outcome** |
| [ ]  **Not known at this date** | [ ]  **Uneventful *(normal/healthy baby)*** | [ ]  **Still birth** | [ ]  **Induced abortion** |
| [ ]  **Spontaneous abortion** | [ ]  **Neonatal death** | [ ]  **Birth defects *(provide details in Other Pregnancy Information section below)*** |
| **Date of above outcome:** |       |

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| **Delivery Information *(if applicable)*** |
| **Date of delivery**: |       | **Mode of delivery:** |       | **Gestation** (weeks): |       | **Gender:**  | [ ]  Male [ ]  Female | **Weight** (kg): |       |
| **Any antenatal problems:** |       | **Any postnatal problems:** |       |

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| **Other Pregnancy Information***Include concurrent conditions, medical history, past pregnancies, complications during birth, birth defects etc. Continue on a separate sheet if necessary.* |
|       |
| **Name of Principal Investigator:***(or delegated medically qualified person)* |       | **Signature:**  |  | **Date:**  |       |
| **Name of person completing the form:** *(if different to person above)* |       |