**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.

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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:** |  |

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

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 |  |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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:** |  | | | |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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)* |  | | | | |