**PREGNANCY REPORTING FORM – CTIMPs**

The Investigator is responsible for reporting all pregnancies, in accordance with the Standard Operating Procedure for the Recording, Management and Reporting of Adverse Events by Investigators (JRO/INV/S05) and as defined by the protocol, to **UCL Joint Research Office (JRO) immediately** (within **24hrs**) of site awareness:

**Email: sae@ucl.ac.uk**

**COMPLETION GUIDELINES:**

* The report fields can be completed electronically (in MS Word) or a blank report can be printed and completed using a black pen.
* All dates should be entered using the **DD-MMM-YYYY** format, i.e. 08-JUN-2018.
* Ensure **no patient identifiable data** is sent to the JRO, and only send supporting documentation if requested by the JRO.
* The Pregnancy Reporting Form should be filed in the Investigator Site File, along with all relevant correspondence.

**Investigator Signature**

* The Investigator **must sign and date** where indicated on the last page. The completed report should be printed, signed and scanned, or an electronic signature added to a pdf file of the report, using Adobe or DocuSign.

**Follow-up Reports**

* Where information is not available at the time of reporting the pregnancy ensure all sections are completed on a follow-up report:
* If only minor updates are needed, ensure all follow-up information added to the initial report is initialled and dated, or if completing the form electronically use tracked changes in MS Word.
* Ensure the ‘type of report’ box is updated to ‘follow-up’ with the follow-up report number added, and the report is resigned and dated by the Investigator.
* If major updates are needed complete a new Pregnancy Reporting Form
* All follow-up reports must be emailed to the JRO **within 24hrs** of site awareness of the follow-up information.

|  |  |
| --- | --- |
| **Study Sponsor Number:**  | ***ADD NUMBER*** |
| **Study Name:**  | ***ADD SHORT 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** *amend/pre-fill per protocol* |
| **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? *Remove for open label trials* | [ ]  Y [ ]  N |

|  |
| --- |
| **Non-Investigational Medicinal Product(s) (nIMP(s))** *remove this section if no nIMPs specified in trial* |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End Date** |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |

|  |
| --- |
| **Concomitant Medication** *(Ensure information reflects CRF)* |
| **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)* |       |