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| Once you have become aware of a participant or spouse pregnancy, please complete, scan & email this signed form to the GCP team: research.safety@qmul.ac.uk (or to the trial co-ordinator’s fax number if multi-site study) WITHIN 24 hours of learning of the pregnancy. Print it and file JRMO acknowledgement in your TMF along with the original form. |
| Report type: | Initial [ ]  Follow-up [ ]   |
| **If the study is multi-site, the section below should be completed by the main site trial coordinator prior to sending the template to the sites** |
| Full title of the study: |  |
| Sponsor: | Barts Health [ ]  Queen Mary [ ]  |
| IRAS Number: |  |
| Public Registration Number: |  |
| Chief investigator: | Name: Email:Phone Number: |
| Is this a double-blind study? | Yes [ ]  No [ ] If yes are the code break procedures in place with pharmacy? Yes [ ]  No [ ]  |
| Name of ALL IMPs and/or medical devices | IMP 1: |  |
| IMP 2: |  |
| IMP 3:  |  |
| IMP 4: |  |
| **This section should be completed by the SITE:** |
| Subject identification code: |  | Participant initials |  |
| Participant or partner: | Participant [ ]  Partner [ ] If partner,date of consent (for pregnancy & outcome follow-up): \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| Patient’s age at time of event: |  | Sex: | M [ ]  F [ ]  |
| Principal investigator: | Name: Email:Phone Number: |
| Trial coordinator local site: | Name: Email:Phone Number: |
| Name of reporting host institution: | Site name:Site number:  |
| Date of site becoming aware of the event:  | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| **1. MATERNAL INFORMATION** |
| Age at time of event: |  |
| Date of last menstrual period: | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| Expected date of delivery: | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| Method of contraception |  |
| Contraception used as instructed | Yes [ ]  No [ ]  Uncertain [ ]  |
|  **2. MEDICAL HISTORY** (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy) |
|  |
| **3. PREVIOUS OBSTETRIC HISTORY** (provide details on all previous pregnancies, including termination or stillbirth) |
|  | Gestation week | Outcome including any abnormalities |
|  |  |  |
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|  |  |  |
|  |  |  |
| **4. DRUG INFORMATION** (list all therapies taken prior to and during pregnancy) |
| Name of drug | Daily dose | Route | Date started | Indication | Date stopped | Treatment start(week of pregnancy) | Treatment stop (week of pregnancy) |
|  |  |  | \_\_\_/\_\_\_/\_\_\_ (dd) (mm) (yy) |  | \_\_\_/\_\_\_/\_\_\_ (dd) (mm) (yy) |  |  |
|  |  |  | \_\_\_/\_\_\_/\_\_\_ (dd) (mm) (yy) |  | \_\_\_/\_\_\_/\_\_\_ (dd) (mm) (yy) |  |  |
|  |  |  | \_\_\_/\_\_\_/\_\_\_ (dd) (mm) (yy) |  | \_\_\_/\_\_\_/\_\_\_ (dd) (mm) (yy) |  |  |
| **5. PRENATAL INFORMATION**  |
| Have any specific tests e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far | Yes [ ]  No [ ]  Not known [ ] If Yes, please specify:  |
| Test: | Test date: |
| Result: |
| **6. PREGNANCY OUTCOME****Please ensure to collect and report this information to the sponsor within one week of outcome OR within 24 hours if an adverse outcome is learnt** |
| Termination of pregnancy: | [ ]  Yes [ ]  NoIf yes:[ ]  Planned[ ]  Spontaneous  | Delivery:  | [ ]  Yes [ ]  NoIf yes:[ ]  Normal[ ]  Forceps[ ]  Caesarean For Caesarean, please specify:Elective [ ]  Emergency[ ]   |
| Please specify the reason and any abnormalities (if known): | Maternal complications or problems related to birth: |
| Date of termination | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) | Date of delivery | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| **7. MATERNAL PREGNANCY ASSOCIATED EVENTS**If the mother experiences an SAE during the pregnancy, please indicate here and complete an SAE form and submit to JRMO immediately. |
| SAE: | Yes [ ]  No [ ]   |
| **8. CHILD OUTCOME** |
| Congenital  | Yes [ ]  No [ ]   | If any congenital abnormalities, please specify:  |
| Stillbirth | Yes [ ]  No [ ]   | If yes:Date of stillbirth: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| Admission to neonatal intensive care unit | Yes [ ]  No [ ]   | If yes: Date of admission: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)Reason for admission:  |
| Neonatal death | Yes [ ]  No [ ]   | Sex: | M [ ]  F [ ]   |
| Head circumference: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_cm | Apgar scores: | 1 min |  |
| Weight: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | 5 mins  |  |
| Height: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_cm | 10 mins |  |
| **9. CHILD OUTCOME FOLLOW UP**This form should be adapted per study to include child follow-up in applicable studies (see protocol) |
| Duration of child follow-up (please state number of weeks/months/years): |  |
| **11. MATERNAL OUTCOME** |
| Complications: | Yes [ ]  No [ ]   |
| Death: | Yes [ ]  No [ ]  If yes:Date of death: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)Cause of death: Any other information: |
| **12. ASSESSMENT OF SERIOUSNESS (OF PREGNANCY OUTCOME)** |
| [ ]  Life-threatening | [ ]  Stillbirth/neonate died Date of death \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year) |
| [ ]  Involved prolonged inpatient hospitalisation |
| [ ]  Results in persistent or significant disability/incapacity |
| [ ]  Congenital anomaly/birth defect |
| [ ]  Other significant medical eventsPlease specify: |
| **13. ASSESSMENT OF CAUSALITY (OF PREGANANCY OUTCOME)**Please indicate the relationship between IMP and pregnancy outcome |
| Is the pregnancy outcome likely to be a reaction to one of the IMPs within the study? | IMP \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_likely or possibly [ ]  Related [ ]  Unrelated |
| **14. ADDITIONAL INFORMATION** |
| Person completing the form if not the PI | Name: Medical profession (i.e. doctor or dentist):Email:Phone Number:Signature: Date:  |
| Investigator’s Name | Please PRINT |
| Investigator’s Signature |  | Date: |

**For Multi-site studies only**

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| --- | --- |
| Date form RECEIVED by CI’s team from external site: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  | CI Reviewed by: Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  |

**For JRMO office use only**

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| Date form RECEIVED by R&D team: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  | Reviewed by: Date reviewed: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  |
| Date form REVIEWED by sponsor obstetrician:\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  | Reviewed by: Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  |
| **For SUSAR only:** |
| Date reported to the MHRA:Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (date) (month) (year)  |