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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](mailto: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  No  If yes:  Planned  Spontaneous | | | | Delivery: | | | | | | Yes  No  If 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 events  Please 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**

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

|  |  |
| --- | --- |
| 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) | |