Quality Control Document:

Pregnancy Notification Form

# Purpose

In the event that a participant, or their partner, falls pregnant during their involvement in a research project, their pregnancy will require monitoring and follow-up. In terms of the project, a pregnancy would not typically be considered to be an adverse event or serious adverse event. However, it is important to monitor a pregnancy’s outcome in order to provide SAE data on congenital anomalies or birth defects. This template can be used to produce a pregnancy notification form that is specific to the research project. Its use is optional.

# Instructions

1. Remove this first instruction page.
2. Update the identifier in the header e.g. study/trial identifier or research group.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. This form may be completed by a person who has been delegated the duty.
5. If the participant’s partner is pregnant, explicit consent will be needed from them to collect their pregnancy data. Researchers are also encouraged to develop an information sheet.

* Researchers may wish to combine the information sheet and consent form, and may wish to term it ‘Release of Medical Information Form’.

1. All completed versions of this record, along with all related correspondence, should be filed in the relevant study/trial master file.

# Related documents

* UoB-AES-QCD-001 Serious Adverse Event (SAE) Form Template
* UoB-AES-QCD-002 Internal Process Example for Serious Adverse Event (SAE) Handling
* UoB-AES-SOP-001 Adverse Event Reporting

Note the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# Pregnancy Notification Form

## Is the participant or their partner pregnant?

|  |  |
| --- | --- |
| □ Participant | □ Partner\* |

\*If a participant’s partner falls pregnant, provide them with relevant information (e.g. an information sheet) and a consent form. Their explicit consent must be obtained before fully completing this form.

## Participant details

|  |  |  |
| --- | --- | --- |
| **Participant’s ID number:** |  | |
| **Participant’s initials:** |  | |
| **Date of birth:** | DD / MON / YYYY | |
| **Site:** |  | |
| **Investigator:** |  | |
| **Sex:** | □ Male | □ Female |

## Report details

|  |  |  |
| --- | --- | --- |
| **Date:** | DD / MON / YYYY | |
| **Initial or final report?** | □ Initial report | □ Final report |
| **Has the mother given consent for pregnancy monitoring?** | □ Yes | □ No |
| Note: if consent has not been given do not complete the rest of this form | |

## Pregnancy information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date of last menstrual period:** | DD / MON / YYYY | | | |
| **Date pregnancy confirmed:** | DD / MON / YYYY | | | |
| **Expected date of delivery:** | DD / MON / YYYY | | | |
| **Contraception used as instructed?**  Note: specify details in the comments box below | □ Yes | □ No | | □ Uncertain |
| □ No instructions for contraception | | | |
| **Onset of labour (for deliveries after 22 weeks’ gestation):** | □ Spontaneous | | □ Induced | |
| **Pregnancy outcome:** | □ Healthy baby | | | |
| □ Induced abortion, own choice  If the pregnancy resulted in any of the following outcomes, please also complete an SAE form. See Serious Adverse Event Form Template (UoB-AES-QCD-001). | | | |
| □ Birth defects, or baby requiring admission to neonatal | | | |
| □ Therapeutic abortion, requested for medical reasons | | | |
| □ Miscarriage | | | |
| □ Still birth | | | |
| □ Neonatal death | | | |
| **Date of above outcome:** | DD / MON / YYYY | | | |

## Comments

|  |
| --- |
| Note: the mother’s relevant medical history and any medication taken during pregnancy should be documented in the medical notes. |

## Signature

|  |  |
| --- | --- |
| **Completed by** | |
| Name: |  |
| Function: |  |
| Date: | DD / MON / YYYY |
| Signature: |  |
| Note: you must have signed the Site Signature & Delegation Log | |