Form: Pregnancy Notification Reporting Form

Once you have become aware of an SAE, please email this signed form to research.safety@qmul.ac.uk and the trial manager on Blizard-ILANA@qmul.ac.uk WITHIN 24 hours of learning of the event.

Report type

- Initial
- Follow-up

Who is this form being completed?

- Participant
- Participant’s partner

If the project 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 trial: ILANA- Implementing Long-Acting Novel Antiretrovirals

Sponsor: QMUL

IRAS number: 313217

Chief investigator:

Name: Prof. Chloe Orkin
Email: c.m.orkin@qmul.ac.uk
Phone Number: 020 7377 7457

This section should be completed by the SITE:

Mothers year of birth:

Date of last menstrual period:

Estimated date of delivery:

Was the mother using a method of contraception?

- Yes
- No

If yes, please specify:
Type of conception:

- [ ] Normal (includes use of fertility drugs)
- [ ] IVF (in vitro fertilisation)

Number of previous pregnancies:

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Previous pregnancies:

- [ ] Pre-term
- [ ] Full-term

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If applicable, record the number in the appropriate categories below:

- [ ] Normal births
Record details of children born with defects:

Are there any additional factors that may have an impact on the outcome of this pregnancy?

- Yes
- No

If yes, please specify
FATHER'S RELEVANT MEDICAL/FAMILY HISTORY
Only recorded if required by the protocol and Informed Consent of the father has been obtained. (Include habitual exposures such as alcohol/substance abuse, chronic illnesses, familial birth defects/genetic/ chromosomal disorders and medication use)
concomitant medications, attach a copy of the Concomitant Medications CRF page.

Select medication

Was the subject withdrawn from the study as a result of this pregnancy?

☐ Yes

☐ No

Additional Information

Principal investigator:

Name:
Subject: _______________
Data event: _______________
Form: Pregnancy Notification Reporting

Phone Number:

Name of reporting host institution:

Site name:
Subject: ____________
Data event: ____________
Form: Pregnancy Notification Reporting

Last saved on form version: ____________ 10:21
Current Form version: 1.0 (2022-07-07)
Study version: 5

Please answer this question

Site number:

Please answer this question

Person completing the form if not the PI

Name:
Subject: _______________
Data event: _______________
Form: Pregnancy Notification Reporting
Form
Last saved on form version: _____________ 10:21
Current Form version: 1.0 (2022-07-07)
Study version: 5

Phone Number:

Date

Investigator’s Name

Please answer this question
Please note in cases where the PI is not readily available to sign the pregnancy form a sub investigator may sign in their absence to meet the 24-hour deadline. The PI can then sign the form on their return.

On receipt the JRMO will:

- Acknowledge receipt
- Enter information in to the sponsors database
- Request clarification/additional information
- Save this document