Subject: _____
Data event: _____
Form: Pregnancy Notification Reporting Form
Last saved on form version: _____
Current Form version: 1.0 (2022-07-07)
Study version: 5

Study: ILANA
Filled out by: _____
Filled out date: _____
Printed Time: 2023-01-16 10:21

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Form: **Pregnancy Notification Reporting 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

Please answer this question

Who is this form being completed?

- ○ Participant
- ○ Participant's partner

Please answer this question

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

Subject: _____
Data event: _____
Form: Pregnancy Notification Reporting Form
Last saved on form version: _____
Current Form version: 1.0 (2022-07-07)
Study version: 5

Study: ILANA
Filled out by: _____
Filled out date: _____
Printed Time: 2023-01-16 10:21

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Email: c.m.orkin@qmul.ac.uk

Phone Number: 020 7377 7457

This section should be completed by the SITE:

Mothers year of birth:

.....

Please answer this question

Date of last menstrual period:

.....

Please answer this question

Estimated date of delivery:

.....

Please answer this question

Was the mother using a method of contraception?

- ○ Yes
- ○ No

Please answer this question

If yes, please specify:

Please answer this question

Type of conception:

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

Please answer this question

Number of previous pregnancies:

Please answer this question

Previous pregnancies:

- ○ Pre-term
- ○ Full-term

Please answer this question

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

- ○ Normal births

- ○ Spontaneous abortion
- ○ Stillbirths
- ○ Elective abortion
- ○ Children born with defects
- ○ Other
- ○ Not applicable

Please answer this question

Record details of children born with defects:

.....

Please answer this question

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

- ○ Yes
- ○ No

Please answer this question

If yes, please specify

Please answer this question

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)

Please list all medications (including study medications) the subject received during the study period (e.g. prescription, OTC, vaccines, recreational, alcohol, etc.). If there are extensive

concomitant medications, attach a copy of the Concomitant Medications CRF page.

Select medication

Please answer this question

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

- ○ Yes
- ○ No

Please answer this question

Additional Information

Please answer this question

Principal investigator:

Name:

Please answer this question

Email:

Please answer this question

Phone Number:

Please answer this question

Trial coordinator local site:

Name:

Please answer this question

Email:

Please answer this question

Phone Number:

Please answer this question

Name of reporting host institution:

Site name:

Please answer this question

Site number:

Please answer this question

Person completing the form if not the PI

Name:

Please answer this question

Medical profession (i.e. doctor or dentist):

Please answer this question

Email:

Please answer this question

Phone Number:

Please answer this question

Date

Please answer this question

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 24hour 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