ECUSTEC Pregnancy Notification Form

INITIAL REPORT TO BE COMPLETED ON BECOMING AWARE THAT THE PATIENT IS PREGNANT, OR THAT THE PATIENT'S FEMALE PARTNER HAS BECOME PREGNANT. UPDATED INFORMATION TO BE PROVIDED ON FOLLOW UP REPORT ONCE AVAILABLE.

Patient Details

Trial Number: ☐☐☐☐☐	Date of Birth: __ __ __ / __ __ __ __ (mon/yyyy)
Site Name:	Trial Investigator:

Report Details

☐ Initial Report ☐ Follow-Up Report Pregnancy Notification No. ☐☐☐☐☐ / ☐☐

Report Type:	
☐	Notification of pregnancy in female participant **(please complete entire form)**
☐	Notification of pregnancy in male participant's partner **(complete relevant sections only)**

Maternal Information

Date of last menstrual period	Date pregnancy confirmed	Expected date of delivery
(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)

Method of contraception:

Contraception used as instructed in protocol? ☐ Yes ☐ No ☐ Uncertain

Have any specific tests e.g. amniocentesis, ultrasound etc been performed during the pregnancy so far?

☐ Yes ☐ No ☐ Uncertain

Drug Information (list all medications taken prior to, or during, pregnancy which may interact/influence the pregnancy)

Drug Name	Dose (including units and frequency)	Route	Start Date	Ongoing? Y	Ongoing? N	Stopped Date (if relevant)	Indication
			(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	
			(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	
			(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	

Pregnancy Outcome

Abortion? ☐ Yes ☐ No ***If yes,*** ☐ Therapeutic ☐ Planned

Date of Abortion: (dd/mon/yyyy) ☐ Spontaneous (miscarriage– before 24 completed weeks of pregnancy)

Delivery? ☐ Yes ☐ No ***If yes, was baby*** ☐ Healthy baby ☐ Stillbirth (after 24 weeks of pregnancy)

☐ Neonatal death (within first 28 days of life)

☐ Abnormal (describe abnormality) ____________________

Date of Delivery: (dd/mon/yyyy)

Comments

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

DETAILS OF PERSON REPORTING

Signature of Person Reporting (you must have signed the site delegation log):	Name of Person Reporting: Position:
Date Completed: (dd/mon/yyyy)	
Signature of Principal Investigator	Date PI Signed: (dd/mon/yyyy)