Protocol Number: _____ Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Birth Order Number (if singleton, enter '1'): ____

Instructions: Complete the form for each fetus; sign the form with a digital signature; save a copy for your records and turn in the signed form to OSROSafety@NIH.gov.

Pregnancy outcome (for this fetus):
- ☐ Live birth
- ☐ Still birth (≥ 20 weeks)
- ☐ Spontaneous miscarriage (<20 weeks)
- ☐ Other (Specify)

If miscarriage, still birth, or otherwise meets the criteria for AE/SAE, document the event as AE/SAE, as appropriate.

Pregnancy-related Information

Indicate the source of information: (may check yes to more than one)

Pregnant person:	☐ No	☐ Yes
Family member:	☐ No	☐ Yes
Physician/medical chart:	☐ No	☐ Yes
Other:	☐ No	☐ Yes, specify: _____

Pregnancy Outcome

End of pregnancy weight:

Date of end of pregnancy weight: _____ (dd/MMM/yyyy)
- ☐ Exact date
- ☐ Day unknown
- ☐ Day and month unknown
- ☐ Day, month, and year unknown

Weight: _____

Weight units:
- ☐ Pounds
- ☐ Kilograms

Labor, Delivery, and Post-Partum Information

Did the individual experience any of the pregnancy complications listed below during labor, delivery, or post-partum? ☐ No ☐ Yes ☐ Unknown

If yes, document the event as AE/SAE, as appropriate.

Abruptio placentae	Eclampsia	GBS-positive
Abnormal bleeding/hemorrhage	Emergency Cesarean section due to fetal distress	Oligohydramnios
Anaphylaxis		Placenta previa
Bacteremia	Endometritis	Polyhydramnios
Chorioamnionitis	Fetal distress	Pre-eclampsia
Coagulation disorders	Fever > 100.4°F or 38.0°C	Pregnancy induced hypertension
Cord prolapse	Gestational diabetes	Preterm labor

Did the individual experience any other complications during this pregnancy? ☐ No ☐ Yes ☐ Unknown

If yes, document the event as AE/SAE, as appropriate.

Protocol Number: _____ Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Birth Order Number (if singleton, enter '1'): ____

Labor, Delivery, and Post-Partum Information

Was there any fetal distress during labor and delivery? ☐ No ☐ Yes ☐ Unknown

If yes, document the event as AE/SAE, as appropriate.

Neonatal Outcome – Live Birth and Still Birth Only

Date of live birth or still birth: _____

Delivery: ☐ Vaginal ☐ Cesarean Section

Gender: ☐ Male ☐ Female

Infant/fetal gestational age at live birth or still birth: ____ weeks and ____ days

Size for gestational age: ☐ SGA ☐ AGA ☐ LGA

Infant Measurements

Birth weight: Weight units: ☐ Pounds ☐ Kilograms Weight: _____

Length: Length units: ☐ Inches ☐ Centimeters Length: _____

Frontal occipital circumference (FOC): FOC units: ☐ Inches ☐ Centimeters FOC: _____

Apgar score, 1 minute (leave blank for still birth): _____

Apgar score, 5 minutes (leave blank for still birth): _____

Cord pH: _____

Congenital anomalies: ☐ No ☐ Yes *(If yes, document the event as AE/SAE, as appropriate.)*

Protocol Number: _____ Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Birth Order Number (if singleton, enter '1'): ____

One-Month Follow-Up – Live Birth Only

Has the infant been diagnosed with any congenital anomalies since birth? *(Not previously reported above)* ☐ No ☐ Yes ☐ Unknown

If yes, document the event as AE/SAE, as appropriate.

Has the infant been ill or hospitalized? (*Do not include well-child visits)* ☐ No ☐ Yes ☐ Unknown

If yes, specify: _____

One or Two-Month Follow-Up – Still Birth Only

Was there an autopsy? ☐ No ☐ Yes ☐ Unknown

If yes, was an etiology for the still birth identified? ☐ No ☐ Yes ☐ Unknown

If yes, specify: _____

Pregnancy Outcome – Spontaneous Miscarriage Only

Date of pregnancy loss: _____

Fetal gestational age: ____ weeks and ____ days

Any abnormality in product of conception? ☐ No ☐ Yes ☐ Unknown

If Yes, specify: _____

Protocol Number: ________________________

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Birth Order Number (if singleton, enter '1'): ____

Study Interventions

List all study interventions that are part of the IND, and commercial products being used to test the research hypothesis:

Study Intervention		Diagnosis for Use	
Actual Dose Given Prior to SAE		Route	
First Dose		Frequency	
Last Dose (prior to SAE)		Action Taken	Select

Study Intervention		Diagnosis for Use	
Actual Dose Given Prior to SAE		Route	
First Dose		Frequency	
Last Dose (prior to SAE)		Action Taken	Select

Study Intervention		Diagnosis for Use	
Actual Dose Given Prior to SAE		Route	
First Dose		Frequency	
Last Dose (prior to SAE)		Action Taken	Select

Study Intervention		Diagnosis for Use	
Actual Dose Given Prior to SAE		Route	
First Dose		Frequency	
Last Dose (prior to SAE)		Action Taken	Select

Click button below to add another Study Interventions page.

Add Page

Protocol Number: _____ Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Birth Order Number (if singleton, enter '1'): ____

Comments:

Signature: