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

Instructions: When completing the form for the first time, fill in the requested information in Section A. Initial Report. Save the file prior to signing it so that the form is available if and when follow-up reports are made. Sign the Initial Report with a digital signature. Turn in the signed form to OSROSafety@NIH.gov.

When a follow-up report is made, open the unsigned form and complete Section B. Follow-Up Report. Save the file prior to signing it so that the form is available if and when additional follow-up reports are made. Sign the Follow-Up Report with a digital signature. Turn in the signed form to OSROSafety@NIH.gov.

Pregnancy has been reported under the protocol: ☐ No ☐ Yes

A. Initial Report

Date of initial report: _____

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:	_____

Indicate who was pregnant or if pregnancy was suspected:

☐ Pregnancy of participant

☐ Pregnancy of participant's partner

☐ Suspected pregnancy

Protocol Number: ________________________ Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

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: ___ ___ ___ ___ ___ ___ ___ ___

Current Pregnancy Information

Number of fetuses: _____

Date of last menstrual period: _____ (dd/MMM/yyyy)

Estimated delivery date: _____ (dd/MMM/yyyy)

How was estimated delivery date determined?
- ☐ Last menstrual period
- ☐ Ultrasound

If ultrasound, estimated date of exam: _____ (dd/MMM/yyyy)

Height:

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

Height units:
- ☐ Inches
- ☐ Centimeters

Height: _____

Pre-pregnancy weight:

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

Weight units:
- ☐ Pounds
- ☐ Kilograms

Weight: _____

Previous Pregnancy Information

Gravida (total number of pregnancies including the current pregnancy): _____ ☐ Unknown

Excluding the current pregnancy, provide numbers for the following (record "0" if none):

Para events

Live births: _____ ☐ Unknown

Extremely preterm (EPT) births (< 25 weeks): _____ ☐ Unknown

Very preterm (VPT) births (25 0/7 – 31 6/7 weeks): _____ ☐ Unknown

Early preterm births (32 0/7 – 33 6/7 weeks): _____ ☐ Unknown

Late preterm births (34 0/7 – 36 6/7 weeks): _____ ☐ Unknown

Early term births (37 0/7 – 38 6/7 weeks): _____ ☐ Unknown

Full term births (39 0/7 – 40 6/7 weeks): _____ ☐ Unknown

Late term births (41 0/7 – 41 6/7 weeks): _____ ☐ Unknown

Post term births (≥ 42 0/7 weeks): _____ ☐ Unknown

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

Previous Pregnancy Information

Stillbirths (≥ 20 weeks): _____ ☐ Unknown

Spontaneous miscarriages (< 20 weeks): _____ ☐ Unknown

Therapeutic abortions: _____ ☐ Unknown

Therapeutic abortions are defined as abortions due to medical reasons for the mother or fetus.

Any major congenital anomalies with a previous pregnancy? ☐ No ☐ Yes ☐ Unknown

If yes, specify:

B. Follow-Up Information

Pregnancy Follow-Up *(Update as applicable during follow-up)*

Was follow-up contact made with the individual during the pregnancy? ☐ No ☐ Yes

If yes, list dates that contact was made, and update the other sections of this form, as necessary.

#	Date	#	Date	#	Date
1		5		9	
2		6		10	
3		7		11	
4		8		12	

Pregnancy Status *(Update as applicable during follow-up)*

Pregnancy status:
- ☐ Pregnancy ongoing
- ☐ Outcome known
- ☐ Outcome unknown (participant lost to follow-up or refused to provide further information)

For known pregnancy outcomes, record pregnancy outcome data for each fetus using F07-301-S01 CCR Pregnancy Outcome Form.

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

Current Pregnancy Information *(Update as applicable during follow-up)*

Did the individual experience any of the complications listed below during this pregnancy? ☐ No ☐ Yes ☐ Unknown

If yes, report Adverse Event/Serious Adverse, as appropriate.

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

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

If yes, document the event per CCR requirements, as appropriate.

Pregnancy Risk Factors *(Update as applicable during follow-up)*

Did the individual use tobacco products, drink alcohol, or use other illicit drugs during this pregnancy? ☐ No ☐ Yes ☐ Unknown

Did the individual take any medications (over the counter and/or prescription) during the pregnancy? ☐ No ☐ Yes ☐ Unknown

If yes, document on the Concomitant Medications List.

Comments:

Signature: