

	Office of Sponsor and Regulatory Oversight	Document #: F07-301-S01
	CCR Pregnancy Outcome Form	Revision #: 1
		Effective Date: 27APR2020

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	Elective abortion
Spontaneous abortion/miscarriage (<20 wks)	Therapeutic abortion
Still birth (≥ 20 weeks)	

If spontaneous abortion/miscarriage, still birth, or therapeutic abortion, document the event as AE/SAE, as appropriate.

Maternal Information

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

Mother:	No	Yes
Family member:	No	Yes
Physician/medical chart:	No	Yes
Other:	No	Yes, specify: _____

Maternal Outcome

End of pregnancy weight:	Date of end of pregnancy weight:	Weight units:	Weight:
	_____	Pounds	_____ . ____
		Kilograms	
	Exact date		
	Day only unknown		
	Day and month unknown		
	Day, month, and year unknown		

Labor, Delivery, and Post-Partum Information

Did the participant experience any of the maternal complications listed below during labor, delivery, or post-partum?

	No	Yes	Unknown	N/A
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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

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Did the participant experience any other maternal complications during this pregnancy? No Yes Unknown

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

Complete the following sections once for each fetus.

Was there any fetal distress during labor and delivery? No Yes Unknown N/A

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:	Weight:
	Pounds Kilograms	____ . ____
Length:	Length units:	Length:
	Inches Centimeters	____ . ____
Frontal occipital circumference (FOC):	FOC units:	FOC:
	Inches Centimeters	____ . ____

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.)*

