IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Participant Type
Generated On: 19 Oct 2021 01:36:18

Is this participant a mother or an infant?	Mother ☐ Infant ☐
Participant's group	Group 1 - pregnant participant ☐ Group 2 - post-partum participant ☐ Group 3 - infant to group 1 mother ☐ Group 4 - infant to group 2 mother ☐ Group 5 - pregnant participant receiving additional vaccine(s) ☐ Group 6 - infant to group 5 mother ☐
If this participant is a mother, what is the infant's PTID? Add a new log line for each infant being enrolled.	_____
If this participant is an infant, what is the mother's PTID?	_____
If applicable, mark if the participant was previously enrolled in this study.	☐
What was the previous PTID?	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Follow-up Visit Summary
Generated On: 19 Oct 2021 01:36:18

Did the participant complete this visit (or required visit procedures)?	Yes, visit completed ☐ Yes, procedures completed as part of another visit ☐ No, visit missed ☐ No, visit skipped ☐
If "No", end of form.	
If "Yes, procedures completed as part of another visit", at which visit were the procedures completed?	V1 - Screening/Enrollment ☐ V3 - Hospital delivery ☐ V4 - 2w contact/Breast milk collection ☐ V101 - Screening/Enrollment ☐ V102 - Breast milk collection ☐
Visit date:	_____
If "Yes, procedures completed as part of another visit", end of form.	
Did the participant exit/terminate the study at this visit? If "Yes", complete the Study Termination CRF.	Yes ☐ No ☐
Were any new medical conditions/events (including hospitalizations or prolongation of existing hospitalizations) reported at this visit? Include any conditions reported after reviewing with the participant any medical history, obstetric history, and history of respiratory illnesses. If "Yes", update the Medical Event log.	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If "Yes", update the Adverse Event log.	Yes ☐ No ☐
Were any new concomitant medications (as described in the protocol) reported at this visit? If "Yes", update the Concomitant Medications log.	Yes ☐ No ☐
Were any protocol deviations reported at this visit? If "Yes", update the Protocol Deviations log.	Yes ☐ No ☐
Were any additional study procedures or forms completed?	Yes ☐ No ☐
Participant Receipt	☐
Participant Transfer	☐
Physical Exam	☐
SARS-CoV-2 Risk Assessment	☐
SARS-CoV-2 Vaccination	☐
Specimen Collection - Breast Milk	☐

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Adverse Event Y/N
Generated On: 19 Oct 2021 01:36:18

Has the participant experienced an adverse event in association with study procedures during the study?	Yes ☐ No ☐

If "Yes", update the Adverse Event log.

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Adverse Event
Generated On: 19 Oct 2021 01:36:18

Date AE reported to site _____

Adverse event (AE) _____

Is this AE related to a study procedure (e.g., blood collection, breast milk collection)?
- Yes ☐
- No ☐

Onset date _____

At which visit was this adverse event first reported?
- V1.0 - Screening/Enrollment ☐
- V2.0 - Post-Vaccination Serology ☐
- V3.0 - Delivery ☐
- V4.0 - 2w PP Follow-up ☐
- V5.0 - 2m PP Follow-up ☐
- V6.0 - 6m PP Follow-up ☐
- V7.0 - 12m PP Follow-up/Exit ☐
- V101.0 - Screening/Enrollment ☐
- V102.0 - 2w PP Follow-up ☐
- V103.0 - 2m PP Follow-up ☐
- V104.0 - 6m PP Follow-up ☐
- V105.0 - 12m PP Follow-up/Exit ☐
- Interim Visit ☐

If "Interim visit", specify interim visit code. _____

Is the AE still ongoing?
- Yes ☐
- No ☐

If "No", outcome date _____

Severity grade
- Grade 1 (Mild) ☐
- Grade 2 (Moderate) ☐
- Grade 3 (Severe) ☐
- Grade 4 (Potentially life-threatening) ☐
- Grade 5 (Death) ☐

Action taken ☐

Mark "None" or all that apply.

None
- Medication(s) ☐
- Therapeutic procedure/surgery ☐
- Diagnostic procedure ☐
- Other ☐

If "Other", specify (max. 200 characters): _____

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Adverse Event
Generated On: 19 Oct 2021 01:36:18

Status/Outcome If "Severity/Frequency increased" is selected, report as a new adverse event.	Recovered/Resolved ☐ Recovering/Resolving ☐ Recovered/Resolved with Sequelae ☐ Not recovered/Not resolved ☐ Fatal ☐ Severity/Frequency increased ☐
If status or outcome is "Severity/Frequency increased", select adverse event.	_____
Is this a serious adverse event according to ICH/GCP or protocol guidelines? If "Yes", check all that apply.	Yes ☐ No ☐
Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐
Results in persistent or significant disability/incapacity	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
Comments (max. 450 characters):	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Concomitant Medications Y/N
Generated On: 19 Oct 2021 01:36:18

Were any concomitant medications taken?	Yes ☐
	No ☐

If "Yes", update the Concomitant Medications log.

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Concomitant Medications
Generated On: 19 Oct 2021 01:36:18

Medication name _____

Indication _____

Date started _____

Date stopped

Or _____

Ongoing ☐

Dose _____

Dose units

- ☐ Grams
- ☐ Micrograms
- ☐ Milligrams
- ☐ Milliliters
- ☐ Capsules
- ☐ Drops
- ☐ Puffs
- ☐ Sachets
- ☐ Suppository
- ☐ Tablets
- ☐ Units
- ☐ Unknown
- ☐ Other

If "Other", specify: _____

Frequency

- ☐ As needed
- ☐ Daily
- ☐ Twice per day
- ☐ Three times per day
- ☐ Four times per day
- ☐ At hour of wake
- ☐ At hour of sleep
- ☐ Once
- ☐ Other

If "Other", specify: _____

Route

- ☐ Oral
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Topical
- ☐ Inhalation
- ☐ Vaginal
- ☐ Rectal

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Concomitant Medications
Generated On: 19 Oct 2021 01:36:18

	Subcutaneous ☐
	Other ☐
If "Other", specify:	_____
Taken for a reported AE?	Yes ☐
	No ☐
If "Yes", select adverse event.	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Demographics
Generated On: 19 Oct 2021 01:36:18

Date of birth	_____
Age	Fixed Unit: yrs
	_____
Sex assigned at birth	Male ☐
	Female ☐
	Intersex ☐
	Decline to answer ☐
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ☐
	Not reported ☐
	Unknown ☐

Race

Mark all that apply.

American Indian or Alaska Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or other Pacific Islander	☐
White	☐
Other	☐
If "Other", specify	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Enrollment
Generated On: 19 Oct 2021 01:36:18

Enrollment date

If Group 3 infant or Group 6 infant, end of form.

Was the participant enrolled post-vaccination? Yes ☐

If "Yes", end of form. No ☐

If applicable, mark if the participant enrolled in between the first and second dose of a two-dose vaccination series. ☐

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Infant Feeding Assessment
Generated On: 19 Oct 2021 01:36:18

Was a feeding assessment completed?	Yes ☐ No ☐
Date of assessment	_____
Has the infant ever breastfed? If “No”, end of form.	Yes ☐ No ☐
Is the infant currently breastfeeding?	Yes ☐ No ☐
Is the breastfeeding being supplemented with formula?	Yes ☐ No ☐
Has your baby completely weaned from breast milk? (Defined as at least one week without breast milk and no intention of restarting)	Yes ☐ No ☐
If "Yes", date infant last received breast milk	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Inclusion/Exclusion Criteria
Generated On: 19 Oct 2021 01:36:18

Did the participant meet all eligibility criteria?	Yes ☐ No ☐
Eligibility status If "Eligible and enrolled", end of form.	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete screening ☐ Ineligible and enrolled ☐
Date participant was found "Eligible/Not Enrolled", "Ineligible", "Incomplete Screening" or "Ineligible and enrolled"	_____
If "Eligible/Not enrolled", specify (max. 200 characters):	_____
Select reason(s) why participant is "Ineligible".	I1. Pregnant individuals scheduled to receive or have received complete SARS-CoV-2 vaccination series. ☐ I2. Willing and able to provide consent for study participation for herself and for her infant. ☐ I3. Individuals scheduled to receive or who have initiated SARS-CoV-2 vaccination series within first 2 months postpartum. ☐ I4. Willing and able to provide consent for study participation for herself and for her infant. ☐ I5. Pregnant individuals scheduled to receive or have received additional dose(s) of any SARS-CoV-2 vaccine during pregnancy. ☐ I6. Willing and able to provide consent for study participation for herself and for her infant. ☐ I7. 18 years of age or older at time of enrollment. ☐ I8. Understands and agrees to comply with all study procedures. ☐ I9. Agrees to sign medical release for herself and her infant. ☐ E1. Behavioral or cognitive impairment or psychiatric disease that, in the opinion of the investigator, may interfere with the subject's ability to participate in the study. ☐ E2. Any condition, which, in the opinion of the investigators, may pose a health risk or interfere with the evaluation of the study objectives. ☐
If "Investigator decision", specify (max. 200 characters):	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Infant Inclusion/Exclusion
Generated On: 19 Oct 2021 01:36:18

Did the infant enroll? If "Yes", end of form.	Yes ☐ No ☐
If "No", why did the infant not enroll?	Infant consent withdrawal/not provided ☐ Mother not enrolled ☐ Other ☐
If "Other", explain.	_____
If "No", date determined:	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Informed Consent
Generated On: 19 Oct 2021 01:36:18

Date initial informed consent signed	_____
Time initial informed consent signed	_____
Part 1 consent version	_____
Part 2 consent version	_____
Was consent provided for specimen storage/use in secondary research?	Yes ☐ No ☐
If mother participant, was consent provided for breast milk sample collection?	Yes ☐ No ☐
ADDITIONAL INFORMED CONSENTS	
Informed consent date	_____
Informed consent time	_____
Part 1 consent version	_____
Part 2 consent version	_____
Was consent provided for specimen storage/use in secondary research?	Yes ☐ No ☐
If mother participant, was consent provided for breast milk sample collection?	Yes ☐ No ☐

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Interim Visit Summary
Generated On: 19 Oct 2021 01:36:18

Visit date	_____
Interim visit code	_____
Did the participant exit/terminate the study at this visit?	Yes ☐ No ☐
Were any new medical conditions/events (including hospitalizations or prolongation of existing hospitalizations) reported at this visit? Include any conditions reported after reviewing with the participant any medical history, obstetric history, and history of respiratory illnesses. If "Yes", update the Medical Event log.	Yes ☐ No ☐
Were any new adverse events (AEs) reported at this visit? If "Yes", update the Adverse Event log.	Yes ☐ No ☐
Were any new concomitant medications (as described in the protocol) reported at this visit? If "Yes", update the Concomitant Medications log.	Yes ☐ No ☐
Were any protocol deviations reported at this visit? If "Yes", update the Protocol Deviations log.	Yes ☐ No ☐
What was the reason for this interim visit? Select all that apply.	
AE report or follow-up	☐
Completion of missed visit procedures	☐
If "Completion of missed visit procedures", for which visit are procedures being made up?	V1.0 - Screening/Enrollment ☐ V2.0 - Post-Vaccination Serology ☐ V3.0 - Delivery ☐ V4.0 - 2w PP Follow-up ☐ V5.0 - 2m PP Follow-up ☐ V6.0 - 6m PP Follow-up ☐ V7.0 - 12m PP Follow-up/Exit ☐ V101.0 - Screening/Enrollment ☐ V102.0 - 2w PP Follow-up ☐ V103.0 - 2m PP Follow-up ☐ V104.0 - 6m PP Follow-up ☐ V105.0 - 12m PP Follow-up/Exit ☐ Interim Visit ☐
Other	☐
If "Other", specify	_____
What study procedures were completed at this visit? Select all that apply.	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Interim Visit Summary
Generated On: 19 Oct 2021 01:36:18

Infant Feeding Assessment	☐
Infant Specimen Collection	☐
Infant Assessment	☐
Participant Receipt	☐
Participant Transfer	☐
Physical exam	☐
SARS-CoV-2 or COVID-19 Diagnosis	☐
SARS-CoV-2 Risk Assessment	☐
SARS-CoV-2 Vaccination	☐
Specimen Collection - Blood	☐
Specimen Collection - Breast Milk	☐
Ultrasound Results	☐

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Baseline Medical History
Generated On: 19 Oct 2021 01:36:18

Date baseline medical history collected	_____
Targeted Conditions If "Yes" to any targeted condition, update the Baseline Medical History log below.	
Hypertension	Yes ☐ No ☐
Asthma	Yes ☐ No ☐
Cancer	Yes ☐ No ☐
Heart disease	Yes ☐ No ☐
Diabetes	Yes ☐ No ☐
Chronic kidney disease	Yes ☐ No ☐
Autoimmune disease (e.g., rheumatoid arthritis, lupus, HIV) or immunodeficiency (e.g., low antibody levels, hypogammaglobulinemia)	Yes ☐ No ☐
Obesity	Yes ☐ No ☐
Substance use	Yes ☐ No ☐
Does the participant have a history of smoking cigarettes?	Yes ☐ No ☐
Does the participant currently smoke cigarettes?	Yes ☐ No ☐
Does the participant have any other medical history to report? If "Yes", update the Baseline Medical History log below.	Yes ☐ No ☐
Baseline Medical History Log	
Description of medical history condition/event	_____
Start date of medical history condition/event	_____
Is the condition ongoing?	Yes ☐ No ☐
Date medical history/condition ended/resolved	_____
Comments (max. 200 characters):	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Medical Event Y/N
Generated On: 19 Oct 2021 01:36:18

Does the participant have any new medical conditions/events to report?	Yes ☐ No ☐

If "Yes", update the Medical Event log.

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Medical Event
Generated On: 19 Oct 2021 01:36:18

Date medical condition/event reported	
At which visit was this medical condition/event first reported?	V1.0 - Screening/Enrollment ☐ V2.0 - Post-Vaccination Serology ☐ V3.0 - Delivery ☐ V4.0 - 2w PP Follow-up ☐ V5.0 - 2m PP Follow-up ☐ V6.0 - 6m PP Follow-up ☐ V7.0 - 12m PP Follow-up/Exit ☐ V101.0 - Screening/Enrollment ☐ V102.0 - 2w PP Follow-up ☐ V103.0 - 2m PP Follow-up ☐ V104.0 - 6m PP Follow-up ☐ V105.0 - 12m PP Follow-up/Exit ☐ Interim Visit ☐
If "Interim visit", specify interim visit code	
Description of medical condition/event	
Start date of medical condition/event	
Is the condition ongoing?	Yes ☐ No ☐
Date medical condition/event ended/resolved	
Did this medical condition/event result in a new hospitalization or prolongation of existing hospitalization?	Yes ☐ No ☐
Date of admission	
Reason for admission	
Primary diagnosis (name)	
Primary diagnosis (ICD#)	
Secondary diagnosis (name)	
Secondary diagnosis (ICD#)	
Any additional diagnoses (names and ICD#'s)	
Date of discharge	
Select if medical condition/event was fatal:	☐
Comments (max. 200 characters):	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Missed Visit
Generated On: 19 Oct 2021 01:36:18

Target visit date	_____
Reason visit was missed	Unable to contact participant ☐ Participant unable to schedule visit within window ☐ Participant refused visit ☐ Participant incarcerated ☐ Participant admitted to healthcare facility ☐ Participant withdrew from study ☐ Participant deceased ☐ Other ☐
If "Other", specify:	_____
Steps taken to address the missed visit (corrective action plan)	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Neonatal Assessment
Generated On: 19 Oct 2021 01:36:18

Date of assessment	
Birth weight	Fixed Unit: kg
Birth length	Fixed Unit: cm
Birth head circumference	Fixed Unit: cm
Gestational age by examination in weeks If prior to 37 weeks, report preterm birth on Medical Event Log.	Fixed Unit: weeks
Gestational age by examination in days	Fixed Unit: days
1 minute Apgar score	
5 minute Apgar score	
Was the infant admitted to the nursery for a notable medical condition/event?	Yes ☐ No ☐
If "Yes", select applicable Medical Event log line.	
Was the infant admitted to neonatal intensive care unit (NICU)?	Yes ☐ No ☐
If "Yes", select applicable Medical Event log line.	
Was there a need for respiratory support or other life sustaining interventions?	Yes ☐ No ☐
If "Yes", select applicable Medical Event log line.	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Participant Receipt
Generated On: 19 Oct 2021 01:36:18

Name of receiving study site	BCM VTEU ☐
	CHOP - Vanderbilt VTEU sub ☐
	Cincinnati VTEU ☐
	Emory VTEU ☐
	New York - VTEU ☐
	NYU VTEU - Brooklyn ☐
	Rochester VTEU ☐
	Seattle Children's - UW VTEU sub ☐
	UIC - SLU VTEU sub ☐
	UPMC Magee - UMB VTEU sub ☐
Name of transferring study site	BCM VTEU ☐
	CHOP - Vanderbilt VTEU sub ☐
	Cincinnati VTEU ☐
	Emory VTEU ☐
	New York - VTEU ☐
	NYU VTEU - Brooklyn ☐
	Rochester VTEU ☐
	Seattle Children's - UW VTEU sub ☐
	UIC - SLU VTEU sub ☐
	UPMC Magee - UMB VTEU sub ☐
Date participant received at receiving site	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Participant Transfer
Generated On: 19 Oct 2021 01:36:18

Name of transferring study site	BCM VTEU ☐ CHOP - Vanderbilt VTEU sub ☐ Cincinnati VTEU ☐ Emory VTEU ☐ New York - VTEU ☐ NYU VTEU - Brooklyn ☐ Rochester VTEU ☐ Seattle Children's - UW VTEU sub ☐ UIC - SLU VTEU sub ☐ UPMC Magee - UMB VTEU sub ☐
Name of receiving study site	BCM VTEU ☐ CHOP - Vanderbilt VTEU sub ☐ Cincinnati VTEU ☐ Emory VTEU ☐ New York - VTEU ☐ NYU VTEU - Brooklyn ☐ Rochester VTEU ☐ Seattle Children's - UW VTEU sub ☐ UIC - SLU VTEU sub ☐ UPMC Magee - UMB VTEU sub ☐
Visit of last completed contact with participant	V1.0 - Screening/Enrollment ☐ V2.0 - Post-Vaccination Serology ☐ V3.0 - Delivery ☐ V4.0 - 2w PP Follow-up ☐ V5.0 - 2m PP Follow-up ☐ V6.0 - 6m PP Follow-up ☐ V7.0 - 12m PP Follow-up/Exit ☐ V101.0 - Screening/Enrollment ☐ V102.0 - 2w PP Follow-up ☐ V103.0 - 2m PP Follow-up ☐ V104.0 - 6m PP Follow-up ☐ V105.0 - 12m PP Follow-up/Exit ☐ Interim Visit ☐
If "Interim visit", specify Interim visit code	_____
Date participant's records were sent to receiving study site	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Physical Examination
Generated On: 19 Oct 2021 01:36:18

Was a physical exam performed?	Yes ☐ No ☐
Date of exam	_____
BODY SYSTEM	
HEENT	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Neck	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Lymph Nodes	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Heart/Cardiovascular	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Lung/Respiratory	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Abdomen	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Liver	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Spleen	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Genitourinary	Not done ☐ Normal ☐

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Physical Examination
Generated On: 19 Oct 2021 01:36:18

	Abnormal ☐
If "Abnormal", specify:	_____
Extremities	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Neurological	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Skin	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
General appearance	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Other system finding	Not done ☐
	Normal ☐
	Abnormal ☐
If "Other system", specify system:	_____
If "Abnormal", specify:	_____
Comments (max. 200 characters):	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Pregnancy Assessment
Generated On: 19 Oct 2021 01:36:18

Date of assessment	
Date of onset of last menstrual period	
Estimated date of delivery	
Estimated gestational age - weeks	Fixed Unit: weeks
Estimated gestational age - days	Fixed Unit: days
Method used to determine gestational age	Date of onset of LMP ☐ Ultrasound ☐ Other ☐
If "Other", specify (max. 200 characters):	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Pregnancy History
Generated On: 19 Oct 2021 01:36:18

Date pregnancy history collected	_____
Has the participant ever been pregnant before? Do not include the current pregnancy/pregnancy for which the participant is enrolling in the study.	Yes ☐ No ☐
If "No", end of form.	
Number of full term live births (>=37 weeks)	_____
Number of premature live births (Less than 37 weeks)	_____
Number of spontaneous fetal deaths and/or still births (>=20 weeks)	_____
Number of spontaneous abortions (Less than 20 weeks)	_____
Number of therapeutic/elective abortions	_____
Number of ectopic pregnancies	_____
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	Yes ☐ No ☐
If "Yes", specify (max. 200 characters):	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Pregnancy Outcome
Generated On: 19 Oct 2021 01:36:18

Is the outcome of this pregnancy obtainable?	Yes ☐ No ☐
If "No", end of form.	
How many pregnancy outcomes resulted from this reported pregnancy?	_____
If more than one outcome resulted from this pregnancy, enter the corresponding infant PTID (if applicable).	_____
Outcome date	_____
Place of delivery/outcome	Home ☐ Hospital ☐ Clinic ☐ Unknown ☐ Other ☐
If "Other", specify:	_____
Specify outcome If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:".	Full term live birth (greater than or equal to 37 weeks) ☐ Premature live birth (less than 37 weeks) ☐ Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks) ☐ Spontaneous abortion (less than 20 weeks) ☐ Ectopic pregnancy ☐ Therapeutic/elective abortion ☐ Other ☐
"If "Other", specify:	_____
Method	Cesarean delivery ☐ Vaginal delivery - normal, unassisted ☐ Vaginal delivery - assisted (forceps, vacuum) ☐ Other ☐
Provide a brief narrative of the circumstances (max. 400 characters).	_____
Were there any complications related to the pregnancy outcome?	Yes ☐ No ☐
If "Yes', report all conditions on Baseline Medical History or Medical Event log.	
If "No", skip to "Were any fetal/infant congenital anomalies identified?".	

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Pregnancy Outcome
Generated On: 19 Oct 2021 01:36:18

Delivery-related complications. Mark "None" or all that apply. ☐

None

Intrapartum hemorrhage ☐

Postpartum hemorrhage ☐

Non-reassuring fetal status ☐

Chorioamnionitis ☐

Other ☐

If "Other", specify: _____

Non-delivery related complications.Mark "None" or all that apply. ☐

None

Hypertensive disorders of pregnancy ☐

Gestational diabetes ☐

Other ☐

If "Other", specify: _____

Were any fetal/infant congenital anomalies identified? Mark all that apply.

Yes ☐
No ☐
Not assessed ☐
Unknown ☐

Central nervous system, cranio-facial ☐

Central nervous system, spinal ☐

Cardiovascular ☐

Renal ☐

Gastrointestinal ☐

Pulmonary ☐

Musculoskeletal/extremities ☐

Physical defect ☐

Skin ☐

Genitourinary ☐

Chromosomal ☐

Cranio-facial (structural) ☐

Hematologic ☐

Staff initials/Date

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Infectious	☐
Endocrine/metabolic	☐
Other	☐

Describe congenital anomaly/defect (max. 200 characters).

If fetal/infant congenital anomalies were identified, update infant's Medical Event log.

Staff initials/Date

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Test type

- [x] Syphilis
- [ ] Gonorrhea
- [ ] Herpes Simplex
- [ ] Chlamydia
- [ ] Hepatitis B
- [ ] Hepatitis C
- [ ] HIV
- [ ] 3rd Trimester Rectovaginal GBS Screen
- [ ] Gestational Diabetes Screen
- [ ] Screening Urine Culture
- [ ] Prenatal Genetic Screen
- [ ] Other

If "Other", specify: _____

Result

If "positive", report on Baseline Medical History or Medical Event log.

- [ ] Positive
- [ ] Negative
- [ ] Not done

Date of screening _____

Comments (max. 200 characters):

If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for. _____

Test type

- [ ] Syphilis
- [x] Gonorrhea
- [ ] Herpes Simplex
- [ ] Chlamydia
- [ ] Hepatitis B
- [ ] Hepatitis C
- [ ] HIV
- [ ] 3rd Trimester Rectovaginal GBS Screen
- [ ] Gestational Diabetes Screen
- [ ] Screening Urine Culture
- [ ] Prenatal Genetic Screen
- [ ] Other

If "Other", specify: _____

Result

If "positive", report on Baseline Medical History or Medical Event log.

- [ ] Positive
- [ ] Negative
- [ ] Not done

Date of screening _____

Staff initials/Date

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Comments (max. 200 characters):

If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.

Test type

- [ ] Syphilis
- [ ] Gonorrhea
- [x] Herpes Simplex
- [ ] Chlamydia
- [ ] Hepatitis B
- [ ] Hepatitis C
- [ ] HIV
- [ ] 3rd Trimester Rectovaginal GBS Screen
- [ ] Gestational Diabetes Screen
- [ ] Screening Urine Culture
- [ ] Prenatal Genetic Screen
- [ ] Other

If "Other", specify:

Result

- [ ] Positive
- [ ] Negative
- [ ] Not done

If "positive", report on Baseline Medical History or Medical Event log.

Date of screening

Comments (max. 200 characters):

If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.

Test type

- [ ] Syphilis
- [ ] Gonorrhea
- [ ] Herpes Simplex
- [x] Chlamydia
- [ ] Hepatitis B
- [ ] Hepatitis C
- [ ] HIV
- [ ] 3rd Trimester Rectovaginal GBS Screen
- [ ] Gestational Diabetes Screen
- [ ] Screening Urine Culture
- [ ] Prenatal Genetic Screen
- [ ] Other

If "Other", specify:

Result

- [ ] Positive

If "positive", report on Baseline Medical History or Medical Event log.

Staff initials/Date

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	Negative ☐
	Not done ☐
Date of screening	_____
Comments (max. 200 characters):	
If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.	_____
Test type	Syphilis ☐
	Gonorrhea ☐
	Herpes Simplex ☐
	Chlamydia ☐
	Hepatitis B ■
	Hepatitis C ☐
	HIV ☐
	3rd Trimester Rectovaginal GBS Screen ☐
	Gestational Diabetes Screen ☐
	Screening Urine Culture ☐
	Prenatal Genetic Screen ☐
	Other ☐
If "Other", specify:	_____
Result	Positive ☐
If "positive", report on Baseline Medical History or Medical Event log.	Negative ☐
	Not done ☐
Date of screening	_____
Comments (max. 200 characters):	
If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.	_____
Test type	Syphilis ☐
	Gonorrhea ☐
	Herpes Simplex ☐
	Chlamydia ☐
	Hepatitis B ☐
	Hepatitis C ■
	HIV ☐
	3rd Trimester Rectovaginal GBS Screen ☐
	Gestational Diabetes Screen ☐
	Screening Urine Culture ☐
	Prenatal Genetic Screen ☐

_____
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Other ☐

If "Other", specify: _____

Result

If "positive", report on Baseline Medical History or Medical Event log.

Positive ☐
Negative ☐
Not done ☐

Date of screening _____

Comments (max. 200 characters):

If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for. _____

Test type

Syphilis ☐
Gonorrhea ☐
Herpes Simplex ☐
Chlamydia ☐
Hepatitis B ☐
Hepatitis C ☐
HIV ■
3rd Trimester Rectovaginal GBS Screen ☐
Gestational Diabetes Screen ☐
Screening Urine Culture ☐
Prenatal Genetic Screen ☐
Other ☐

If "Other", specify: _____

Result

If "positive", report on Baseline Medical History or Medical Event log.

Positive ☐
Negative ☐
Not done ☐

Date of screening _____

Comments (max. 200 characters):

If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for. _____

Test type

Syphilis ☐
Gonorrhea ☐
Herpes Simplex ☐
Chlamydia ☐
Hepatitis B ☐
Hepatitis C ☐
HIV ☐
3rd Trimester Rectovaginal GBS Screen ■

_____
Staff initials/Date

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Form: Prenatal Testing
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	Gestational Diabetes Screen ☐
	Screening Urine Culture ☐
	Prenatal Genetic Screen ☐
	Other ☐
If "Other", specify:	_____
Result	Positive ☐
If "positive", report on Baseline Medical History or Medical Event log.	Negative ☐
	Not done ☐
Date of screening	_____
Comments (max. 200 characters):	
If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.	_____
Test type	Syphilis ☐
	Gonorrhea ☐
	Herpes Simplex ☐
	Chlamydia ☐
	Hepatitis B ☐
	Hepatitis C ☐
	HIV ☐
	3rd Trimester Rectovaginal GBS Screen ☐
	Gestational Diabetes Screen ■
	Screening Urine Culture ☐
	Prenatal Genetic Screen ☐
	Other ☐
If "Other", specify:	_____
Result	Positive ☐
If "positive", report on Baseline Medical History or Medical Event log.	Negative ☐
	Not done ☐
Date of screening	_____
Comments (max. 200 characters):	
If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.	_____
Test type	Syphilis ☐
	Gonorrhea ☐
	Herpes Simplex ☐
	Chlamydia ☐
	Hepatitis B ☐
	Hepatitis C ☐

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Prenatal Testing
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	HIV ☐
	3rd Trimester Rectovaginal GBS Screen ☐
	Gestational Diabetes Screen ☐
	Screening Urine Culture ■
	Prenatal Genetic Screen ☐
	Other ☐
If "Other", specify:	
Result	Positive ☐
If "positive", report on Baseline Medical History or Medical Event log.	Negative ☐
	Not done ☐
Date of screening	
Comments (max. 200 characters):	
If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.	
Test type	Syphilis ☐
	Gonorrhea ☐
	Herpes Simplex ☐
	Chlamydia ☐
	Hepatitis B ☐
	Hepatitis C ☐
	HIV ☐
	3rd Trimester Rectovaginal GBS Screen ☐
	Gestational Diabetes Screen ☐
	Screening Urine Culture ☐
	Prenatal Genetic Screen ■
	Other ☐
If "Other", specify:	
Result	Positive ☐
If "positive", report on Baseline Medical History or Medical Event log.	Negative ☐
	Not done ☐
Date of screening	
Comments (max. 200 characters):	
If "Screening Urine Culture" or "Prenatal Genetic Screen" is "Positive", specify what it's positive for.	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Protocol Deviations Y/N
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Have any protocol deviations been reported?	Yes ☐
	No ☐

If "Yes", update the Protocol Deviations log.

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Protocol Deviations
Generated On: 19 Oct 2021 01:36:18

Site awareness date	_____
Deviation date	_____
Has or will this deviation be reported to local IRB/EC?	Yes ☐
	No ☐
Type of deviation	Inappropriate enrollment ☐
	Conduct of non-protocol procedure ☐
	Improper AE ☐
	Unreported AE ☐
	Breach of confidentiality ☐
	Physical assessment deviation ☐
	Lab assessment deviation ☐
	Mishandled lab specimen ☐
	Staff performing duties that they are not qualified to perform ☐
	Questionnaire administration deviation ☐
	Counseling deviation ☐
	Use of non-IRB/EC-approved materials ☐
	Informed consent process deviation ☐
	Visit completed outside of window ☐
	Insufficient volume of primary specimen collected ☐
	Other ☐
Description of deviation	_____
Plans and/or action taken to address the deviation	_____
Plans and/or action taken to prevent future occurrences of the deviation	_____
Deviation reported by	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 or COVID-19 Diagnosis
Generated On: 19 Oct 2021 01:36:18

Diagnosis

Has the participant been diagnosed with SARS-CoV-2 infection or COVID-19 disease? (If completing at a follow-up visit, only report any diagnoses that have not already been reported.) Yes ☐ No ☐

If “No”, end of form.

Date of diagnosis _____

Was diagnosis confirmed with laboratory testing? Yes ☐ No ☐

If "Yes", update the SARS-CoV-2 Test Results log.

Symptoms

Did the participant experience any COVID-19 symptoms? Yes ☐ No ☐

If "Yes", mark all that apply.

If "No", go to Clinical Outcome or Severity section.

Fever	☐
If "Fever", record max temperature:	Fixed Unit: degrees F _____
Dyspnea with exertion	☐
Dyspnea at rest	☐
Cough	☐
Hemoptysis	☐
Sputum production	☐
Chest pain	☐
Unable to sleep lying down	☐
Rhinorrhea or nasal congestion	☐
Sore throat	☐
Anosmia	☐
Ageusia	☐
Anorexia	☐
Nausea or vomiting	☐
Diarrhea	☐
Abdominal pain	☐
Fatigue	☐
Myalgia	☐
Headache	☐
Confusion or mental status changes	☐
Chills	☐

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 or COVID-19 Diagnosis
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New skin findings	☐
If "New skin findings", specify:	_____
Other	☐
If "Other", specify:	_____
Overall duration of symptoms	Fixed Unit: days _____
Clinical Outcome or Severity	
Clinical outcome or severity on COVID-19 Ordinal Scale	◯ Ambulatory, no limitations of activities ◯ Ambulatory, limitation of activities and/or requiring home oxygen ◯ Hospitalized, not requiring supplemental oxygen, not requiring ongoing medical care ◯ Hospitalized, not requiring supplemental oxygen, but requiring ongoing medical care (COVID-19 related or otherwise) ◯ Hospitalized, requiring any supplemental oxygen ◯ Hospitalized, receiving non-invasive ventilation or high flow oxygen ◯ Hospitalized, receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO) ◯ Death
If "Hospitalized", what was the date of admission?	_____
If "Hospitalized", what was the date of discharge?	_____
Treatment	
Was the participant enrolled in any experimental treatment trials? If "Yes", specify AND update the Concomitant Medications log.	◯ Yes ◯ No
Specify treatment (max. 200 characters):	_____
Did the participant receive any of the following medications? If "Yes", mark all that apply AND update the Concomitant Medications log.	◯ Yes ◯ No
Remdesivir	☐
Baricitinib	☐
Chloroquine/hydroxychloroquine	☐
Azithromycin	☐
Tocilizumab or other IL-6 pathway inhibitors	☐
Anti-SARS-CoV-2 monoclonal antibody	☐
Convalescent plasma	☐

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Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 or COVID-19 Diagnosis
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Corticosteroids	☐
Off-label immunomodulatory therapy (not in the context of a clinical trial)	☐
Specify (max. 200 characters):	_____
Off-label antiviral therapy (not in the context of a clinical trial)	☐
Specify (max. 200 characters):	_____
Other COVID-19 specific therapy	☐
Specify (max. 200 characters):	_____
Mark if a new SARS-CoV-2 or COVID-19 Diagnosis form is needed to record another diagnosis for this visit.	☐

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 Risk Assessment
Generated On: 19 Oct 2021 01:36:18

Was a SARS-CoV-2 risk assessment done?	Yes ☐
If "No", end of form.	No ☐
Date of assessment	_____
Occupation	
What is the participant's occupation?	_____
What is the category of the participant's occupation?	Healthcare worker ☐
	Emergency response ☐
	Retail or restaurant operations ☐
	Manufacturing or production operations ☐
	Warehouse shipping or fulfillment centers ☐
	Transportation or delivery services ☐
	Border protection or military personnel ☐
	Personal care and in-home services ☐
	Hospitality and tourism worker ☐
	Pastoral, social or public health worker ☐
	Educator or student ☐
	Other ☐
	Unemployed ☐
Does the participant work from home?	Yes, fully working from home ☐
	Yes, partly working from home ☐
	No ☐
	Not applicable ☐
What is the participant's OSHA risk of occupational exposure?	Lower exposure risk ☐
	Medium exposure risk ☐
	High exposure risk ☐
	Very high exposure risk ☐
	Not applicable ☐

Residence

Where does the participant reside?

Mark all that apply.

Single family home (e.g., detached house)	☐
Multi-family home (e.g., multi-generational household with more than 5 people)	☐
High density housing (e.g., apartment complex or condominium with shared entrances, stairs or elevators)	☐
Low density housing (e.g., apartment complex or condominium without shared entrances, stairs or elevators, duplexes)	☐
Long-term care facility	☐

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 Risk Assessment
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Assisted-living facility	☐
Dormitory	☐
RV/Trailer	☐
Hotel room	☐
Shelter	☐
Staying with friend(s)/Couch surfing	☐
Tribal land/Reservation	☐
Other	☐
If "Other", specify:	_____

How many individuals does the participant reside with?

If none, record 0. _____

Exposure

Within the past month, did the participant have exposure to any individuals with confirmed SARS-CoV-2 infection or COVID-19 disease?	Yes ◯ No ◯

If "No", end of form.

Date of last contact with individual	_____
Exposure description (max. 200 characters):	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 Test Results
Generated On: 19 Oct 2021 01:36:18

Specimen collection date	_____
Test result	Positive ☐
	Negative ☐
	Indeterminate ☐
Test type	RT-PCR ☐
	Antibody/serology ☐
	Antigen ☐
	Other ☐
	Unknown ☐
If "Other", specify:	_____
Specimen collection type	Nasal or Nasopharyngeal Swab ☐
	Nasal Wash ☐
	Oropharyngeal Swab ☐
	Saliva ☐
	Blood ☐
	Other ☐
	Unknown ☐
If "Other", specify:	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 Vaccination
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Did the participant receive a SARS-CoV-2 vaccination, that has not already been reported? ☐ Yes ☐ No

If "Yes", report one dose per form.

If "No", end of form.

How was vaccination information obtained? ☐ Vaccination card ☐ Medical records ☐ Other

If "Other", specify _____

Date of vaccination _____

Location ☐ Hospital ☐ Health Department ☐ Pharmacy ☐ Primary care physician's office ☐ Urgent care or walk-in clinic ☐ Mass vaccination site ☐ Other

If "Other", specify _____

Dose ☐ First ☐ Second ☐ Third ☐ Other

If "Other", specify _____

Vaccine manufacturer ☐ Pfizer-BioNTech ☐ Moderna ☐ Johnson & Johnson ☐ AstraZeneca ☐ Novavax ☐ Other

If "Other", specify _____

Did the participant report any important medical events after vaccination such as allergic reactions or anaphylaxis or other events requiring treatment in an emergency room or medical clinic? ☐ Yes ☐ No

If “Yes”, specify below.

Description of medical condition/event _____

Start date of medical condition/event _____

Is the condition ongoing? ☐ Yes ☐ No

Date medical condition/event ended/resolved _____

Did this condition/event result in a new hospitalization or prolongation of existing hospitalization? ☐ Yes

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: SARS-CoV-2 Vaccination
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	No ☐
Date of admission	_____
Date of discharge	_____
Did the participant receive medication for this medical condition/event? If "Yes", update the Concomitant Medications log.	Yes ☐ No ☐
Did this event/condition result in death?	Yes ☐ No ☐
Comments (max. 200 characters):	_____
Mark if a new SARS-CoV-2 Vaccination form is needed to record another vaccination for this visit.	☐

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Specimen Collection - Blood
Generated On: 19 Oct 2021 01:36:18

Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was the minimum required volume obtained?	Yes ☐ No ☐
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Specimen Collection - Breast Milk
Generated On: 19 Oct 2021 01:36:18

Were breast milk samples collected?	Yes ☐ No ☐
Date breast milk samples collected by site	_____
Specimen collection date	_____
Specimen collection method	Hand expression ☐ Pump ☐
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Infant Specimen Collection
Generated On: 19 Oct 2021 01:36:18

Specimen type	Cord blood ■ Serum ☐
Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was the minimum required volume obtained?	Yes ☐ No ☐
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Cord blood ☐ Serum ■
Was specimen collected?	Yes ☐ No ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was the minimum required volume obtained?	Yes ☐ No ☐
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Study Termination
Generated On: 19 Oct 2021 01:36:18

Date of study exit	_____
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ Other medical condition/event ☐ Other ☐
If "Other", specify (max. 200 characters):	_____
If "Adverse event", select applicable adverse event.	_____
If "Other medical condition/event", select applicable Medical Event log line.	_____
If "Death", specify:	Result of a SARS-CoV-2 vaccine reaction ☐ Clinical outcome of a COVID-19 diagnosis ☐ Result of an adverse event ☐ Other medical condition/event ☐
If "Death", enter date of death.	_____

_____
Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Ultrasound Results
Generated On: 19 Oct 2021 01:36:18

Was an ultrasound report available for review?	Yes ☐ No ☐
Date of ultrasound	
Number of fetuses observed on ultrasound	1 ☐ 2 or more ☐
Were any abnormalities observed?	Yes ☐ No ☐
If "Yes", describe:	
Estimated gestational age - weeks	Fixed Unit: weeks
Estimated gestational age - days	Fixed Unit: days

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Vital Signs
Generated On: 19 Oct 2021 01:36:18

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Height	Fixed Unit: cm
Weight	Fixed Unit: kg
When were height and weight measured?	Pre-pregnancy ☐ First trimester ☐ Current visit ☐
BMI calculated	

Staff initials/Date

IDCRC21-0004_Version_3.0_PROD_TP_18OCT2021: ALL
Form: Infant Assessment
Generated On: 19 Oct 2021 01:36:18

Was an infant assessment done?	Yes ◯ No ◯
Date of assessment	_____
Length	Fixed Unit: cm _____
Head circumference	Fixed Unit: cm _____
Weight	Fixed Unit: kg _____
Were any previously unreported fetal/infant congenital anomalies identified?	Yes ◯ No ◯
If "Yes", mark all that apply.	Not assessed ◯
If "No" or "Not assessed", end of form.	Unknown ◯
Central nervous system, cranio-facial	☐
Central nervous system, spinal	☐
Cardiovascular	☐
Renal	☐
Gastrointestinal	☐
Pulmonary	☐
Musculoskeletal/extremities	☐
Physical defect	☐
Skin	☐
Genitourinary	☐
Chromosomal	☐
Cranio-facial (structural)	☐
Hematologic	☐
Infectious	☐
Endocrine/metabolic	☐
Other	☐
Describe congenital anomaly/defect (max. 200 characters):	_____
If fetal/infant congenital anomalies were identified, select Medical Event log line.	_____
If additional fetal/infant congenital anomalies were identified, select Medical Event log line.	_____

_____
Staff initials/Date