Site Number: ___ ___ ___ ___ Participant ID: ___ ___ ___ ___ ___ ___ Participant Letters: ___ ___ ___

Complete this form when the outcome of an active pregnancy becomes known. Complete this form for all participants that become pregnant or have partners who have become pregnant during the course of the trial.

A. PREGNANCY OUTCOME INFORMATION

1. Is the outcome of the pregnancy unknown due to loss of participant to follow-up? * ○ Yes ○ No

2. Date pregnancy ended: * __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

3. Was the pregnancy terminated as a result of an induced abortion? * ○ Yes ○ No ○ Unknown

If YES,

a. Was the reason for the abortion medically indicated? ○ Yes ○ No ○ Unknown

If YES, Complete Adverse Event Report Form

1) Specify reason: _____

4. Did the pregnancy result in a miscarriage? *Complete Adverse Event Report Form ○ Yes ○ No ○ Unknown

5. Did the pregnancy result in a live birth or multiple live births? * ○ Yes ○ No ○ Unknown

6. Did the pregnancy result in a stillbirth? * ○ Yes ○ No ○ Unknown

If YES, Complete Adverse Event Report Form*

a. Did the stillbirth have any congenital malformations? ○ Yes ○ No ○ Unknown

If YES,

1) Specify: _____

b. Did the stillbirth have any other complications? ○ Yes ○ No ○ Unknown

If YES,

1) Specify: _____

7. Record number of infants (both living and deceased) the birth resulted in: * __ __ □ unknown

8. Were there any complications during the delivery? * ○ Yes ○ No ○ Unknown

9. Was an HbA1c measured at any time during the pregnancy? * ○ Yes ○ No ○ Unknown

If YES,

a. Record HbA1c: __ __.__ % □ unknown

b. Date measured: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

10. Is the participant currently breastfeeding? * ○ Yes ○ No ○ Unknown

B. INFANT INFORMATION

Site Number: ___ ___ ___ ___ Participant ID: ___ ___ ___ ___ ___ ___ Participant Letters: ___ ___ ___

	0 1	0 2	0 3
1. Birth Order:			
2. Sex (M/F):	○ M ○ F	○ M ○ F	○ M ○ F
3. Gestational age:	___ ___ wks □ unknown	___ ___ wks □ unknown	___ ___ wks □ unknown
4. Birth weight:	___ ___ ___ ___gm □ unknown OR ___ ___ lbs ___ ___ oz □ unknown	___ ___ ___ ___ gm □ unknown OR ___ ___ lbs ___ ___ oz □ unknown	___ ___ ___ ___ gm □ unknown OR ___ ___ lbs ___ ___ oz □ unknown
5. One minute APGAR score:	___ ___ □ unknown	___ ___ □ unknown	___ ___ □ unknown
6. Five minute APGAR score:	___ ___ □ unknown	___ ___ □ unknown	___ ___ □ unknown
7 Was the infant born with any congenital malformations? If YES, Complete Adverse Event Report Form*	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
a. If YES*, specify:	_____ _____ _____	_____ _____ _____	_____ _____ _____
8 Was the infant born with other complications? If YES, Complete Adverse Event Report Form*	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
a. If YES*, specify:	_____ _____ _____	_____ _____ _____	_____ _____ _____
9.Was the infant admitted to the Neonatal Intensive Care Unit (NICU) at any time*?	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
10 Was the infant discharged from the hospital alive?	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown
If YES, a. Date discharged:	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
If NO*, b. Date of death:	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR	__ __/__ __ __/__ __ __ __ DAY MONTH YEAR
c. Specify cause of death:	_____ _____ _____	_____ _____ _____	_____ _____ _____