Site No: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

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

A. PREGNANCY OUTCOME INFORMATION

1. Indicate the Pregnancy Identification Number: __ __ __ __

The *Pregnancy Identification Number* is located on the subject's initial Pregnancy Confirmation Form (**MMF09**)

2. Is the outcome of the pregnancy unknown due to loss of participant to follow-up? Y N

IF YES, **STOP HERE**

3. Date pregnancy ended: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

4. Was the pregnancy terminated as a result of an induced abortion? Y N

IF YES,

a. Was the reason for the abortion medically indicated? Y N

IF YES*,

1. Specify reason: _____

5. Did the pregnancy result in a spontaneous miscarriage*? Y N

6. Did the pregnancy result in a live birth or multiple live births? Y N

7. Did the pregnancy result in a stillbirth? Y N

IF YES*,

a. Did the stillbirth have any congenital malformations? Y N

IF YES,

1. Specify: _____

b. Did the stillbirth have any other complications? Y N

IF YES,

1. Specify: _____

8. Indicate number of infants (both living and deceased) the birth resulted in: __ __

9. Were there any complications during the delivery? Y N

10. Was an HbA1c measured at any time during the pregnancy? Y N

IF YES,

a. Indicate HbA1c: __ __. __ %

b. Date measured: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

11. Is the participant currently breastfeeding? Y N

* Requires completion of an Adverse Event Report Form (**MMF07**)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site No: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

B. INFANT INFORMATION

Complete Section B to record the details of any live birth(s).

1. Indicate the Pregnancy Identification Number:			__ __ __ __
2. Birth Order:	__ __	__ __	__ __†
3. Indicate sex (M/F):	M F	M F	M F
4. Indicate gestational age:	__ __ wks	__ __ wks	__ __ wks
5. Indicate birth weight:	__ __ __ __gm OR __ __ lbs __ __ oz	__ __ __ __ gm OR __ __ lbs __ __ oz	__ __ __ __ gm OR __ __ lbs __ __ oz
6. **1 minute** APGAR score:	__ __	__ __	__ __
7. **5 minute** APGAR score:	__ __	__ __	__ __
8. Was the infant born with any congenital malformations?	Y N	Y N	Y N
a. IF YES*, specify:	_____ _____	_____ _____	_____ _____
9. Was the infant born with other complications?	Y N	Y N	Y N
a. IF YES*, specify:	_____ _____	_____ _____	_____ _____
10. Was the infant admitted to the Neonatal Intensive Care Unit (NICU) at any time*?	Y N	Y N	Y N
11. Was the infant discharged from the hospital alive?	Y N	Y N	Y N
IF YES, a. Date discharged:	__ __/__ __/__ __ __ __ MM DD YYYY	__ __/__ __/__ __ __ __ MM DD YYYY	__ __/__ __/__ __ __ __ MM DD YYYY
IF NO*, b. Date of death:	__ __/__ __/__ __ __ __ MM DD YYYY	__ __/__ __/__ __ __ __ MM DD YYYY	__ __/__ __/__ __ __ __ MM DD YYYY
c. Specify cause of death:	_____ _____	_____ _____	_____ _____

* Requires completion of an Adverse Event Report Form (**MMF07**)

† If more space is needed, attach additional copies of the second page of this form

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __/__ __/__ __ __ __ (MM DD YYYY)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*