Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

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. Record the Pregnancy Identification Number: __ __ __ __

The *Pregnancy Identification Number* is located on the subject's initial Pregnancy Confirmation Form (**CTL14**)

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: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

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, **Complete Adverse Event Report Form (CTL13)**

1) Specify reason: _____

5. Did the pregnancy result in a miscarriage? **Complete Adverse Event Report Form (CTL13)** 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, **Complete Adverse Event Report Form (CTL13)**

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

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

10. Is the participant currently breastfeeding? Y N

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 Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

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

B. INFANT INFORMATION

1. Indicate the Pregnancy Identification Number:			__ __ __ __
2. Birth Order:	**0 1**	**0 2**	**0 3†**
3. Sex (M/F):	M F	M F	M F
4. Gestational age:	__ __ wks	__ __ wks	__ __ wks
5. Birth weight:	__ __ __ __gm OR __ __ lbs __ __ oz	__ __ __ __ gm OR __ __ lbs __ __ oz	__ __ __ __ gm OR __ __ lbs __ __ oz
6. One minute APGAR score:	__ __	__ __	__ __
7. Five 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:	__ __/__ __ __/__ __ __ __ 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:	_____ _____	_____ _____	_____ _____

* Requires completion of an Adverse Event Report Form (**CTL13**)

† 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: __ __/__ __ __/__ __ __ __ (DAY MONTH YEAR)

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).*