

Site Number:  
Date of Report:  
Person Completing Form:

Participant ID:  
Participant Letters:

Complete this form upon confirmation that a study participant is pregnant, regardless of assigned treatment group. No further study medication should be given.

**Additional form(s) that need to be completed:**

Adverse Event Report Form  
Pregnancy Outcome Report Form (when pregnancy has ended)

**A. PREGNANCY INFORMATION**

1. Date of positive pregnancy test:

\_\_\_ / \_\_\_ / \_\_\_  
DAY MONTH YEAR

2. Date of last menstrual cycle:

\_\_\_ / \_\_\_ / \_\_\_  
DAY MONTH YEAR

3. Estimated date of delivery:

\_\_\_ / \_\_\_ / \_\_\_  
DAY MONTH YEAR

4. Is the participant planning on carrying the pregnancy to term?

Yes  No  Unknown

5. Is the participant willing to continue with future follow-up visits?

Yes  No  Unknown

6. Has the participant's obstetric care provider been informed of her participation in this study?

Yes  No  Unknown

**B. PREGNANCY HISTORY**

1. Record total number of prior pregnancies (not including this one):

\_\_\_  
 unknown

2. Has the participant ever had a pregnancy complication?

Yes  No  Unknown

If YES,

a. Has the participant ever had a miscarriage?

Yes  No  Unknown

b. Has the participant ever had a pregnancy that resulted in a stillbirth?

Yes  No  Unknown

c. Has the participant ever had a pregnancy result in neonatal death?

Yes  No  Unknown

d. Has the participant ever had a pre-term delivery (< 37 gestational weeks)?

Yes  No  Unknown

e. Has the participant ever had a post-term delivery (> 42 gestational weeks)?

Yes  No  Unknown