Site Number: Participant ID:
Date of Report: Participant Letters:
Person Completing Form:

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?	O Yes O No O Unknown
5. Is the participant willing to continue with future follow-up visits?	O Yes O No O Unknown
6. Has the participant's obstetric care provider been informed of her participation in this study?	O Yes O No O Unknown

B. PREGNANCY HISTORY

1. Record total number of <u>prior</u> pregnancies (not including this one):	__ __ □ unknown
2. Has the participant ever had a pregnancy complication?	O Yes O No O Unknown
If YES,	
a. Has the participant ever had a miscarriage?	O Yes O No O Unknown
b. Has the participant ever had a pregnancy that resulted in a stillbirth?	O Yes O No O Unknown
c. Has the participant ever had a pregnancy result in neonatal death?	O Yes O No O Unknown
d. Has the participant ever had a pre-term delivery (< 37 gestational weeks)?	O Yes O No O Unknown
e. Has the participant ever had a post-term delivery (> 42 gestational weeks)?	O Yes O No O Unknown