

Site Number:  
Date of Visit:  
Person Completing Form:

Participant ID:  
Participant Letters:

**A. PREGNANCY MONITORING**

1. Does the participant have reproductive or childbearing potential?  Y  N

If YES, continue.

**IF FEMALE:**

a. Was a urine pregnancy test completed at this visit?  Y  N

If YES,

1) Was the test result positive?  Y  N

If the **pregnancy test** result was **positive**, complete a Pregnancy Confirmation Form. The Coordinating Center must be notified within 24 hours of clinic notification of an active pregnancy in a study participant.

b. Does the subject plan to become pregnant within the next year?  Y  N

c. Is the subject using birth control (abstinence or acceptable method)?  Y  N

Note: Record medications on Concomitant Medications form.