

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.

IF MALE:

a. Is the subject's partner known to be pregnant? Y N

If the **subject's partner is pregnant (unless pregnancy occurred prior to study drug administration)**, 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's partner.

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

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

Note: Record medications on Concomitant Medications form.

