|  |
| --- |
| *Instructions: This form must be completed by the enrolling clinician or clinic coordinator when the patient is a woman of childbearing potential. Women of childbearing potential have not yet reached menopause and have not undergone tubal ligation or hysterectomy.* |

1. “What was the date of your last period?”

**(lstmensdt)**

\_\_ \_\_ / \_\_ \_\_ / 2 0 1 \_\_

Month Day Year

2. “Are you currently pregnant or nursing/ lactating?”

**(mhpreg)**

**STOP!!**

**THE PATIENT IS INELIGIBLE!**

( )0 ( )1

No Yes

3. “Which of the following methods of contraception do you regularly use?”

a) Oral contraceptives (“the pill”) **(mhconoral)** ( )1

b) Hormone implant or patch **(mhhorm)** ( )1

c) IUD **(mhiud)** ( )1

d) Condom or diaphragm in conjunction

with spermicidal gel **(mhconcond)** ( )1

e) Partner vasectomy **(mhvasect)** ( )1

**STOP!!**

**THE PATIENT IS INELIGIBLE!**

f) Not sexually active **(mhnosex)** ( )1

g) None of the above/Don’t know **(mhnone)**

( )1

4. Was a pregnancy test with a negative test result obtained at this visit?

**(mhprtest)**

**STOP! OBTAIN RESULT BEFORE ENROLLING THE PATIENT!**

No ( )0

Yes ( )1

5. Has the patient been informed that she must continue using effective contraception for the duration of the study?

Instruct the patient that she must use effective contraception for the duration of the study. Refer to section 4.4.3 of the Protocol for effective contraception methods.

**(mhinform)**

( )1 ( )0

Yes No

6. Has the patient been informed that she must immediately notify the DREAM staff if she becomes pregnant and stop taking the study supplements?

Instruct patient that she must notify the DREAM staff if she becomes pregnant while enrolled in the study and that she must stop taking the study supplements.

**(mhbepreg)**

( )1 ( )0

Yes No

By my signature below, I confirm that I discussed with the patient the necessity for continued effective contraception for the duration of the study and that if she becomes pregnant she should notify the study staff and stop taking the study supplements. I also confirm that the patient appeared to understand all that was discussed with her.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Coordinator/Investigator Date

7. Last name and certification number of person who completed this form:

a. PRINT Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **(qclname)**

b. Certification #: \_\_\_ \_\_\_ \_\_\_ \_\_\_ **(qcconcert)**

8. Date form was completed:

**(qccompdtc)**

\_\_ \_\_ / \_\_ \_\_ / 2 0 1 \_\_

Month Day Year