

Date Entered: _____

Staff Initials: _____

COMBINE Menstrual Calendar (MCA ver. A)

Center		Participant #		Participant Initials													
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Instructions: The Menstrual Cycle Calendar is a way to record the pattern of a woman's menstrual cycle in a calendar format. It is an important indication of any irregularities and/or missed periods due to early pregnancy. It is first recorded at baseline during the physical exam and continued through the protocol (the form is cumulative). The MM clinician should complete this form as this is an extension of the SAFTEE. Give the participant a calendar to reference when inquiring about dates.

Instructions for Completing the Menstrual Cycle Chart

- ◆ Place an **(X)** in the box of the **first** day of the last period, through the **last** day of bleeding.
- ◆ At baseline, do the same for the 2 prior menstrual cycles.
- ◆ At each visit, mark any day where there has been any spotting **(S)** since the last visit.
- ◆ A pregnancy test must be done prior to randomization on all female patients, unless menopausal (no period >1 year), post-hysterectomy, or tubal ligation.
- ◆ If it has been 35 or more days since the first day of the last period, a pregnancy test must be done at the visit. A pregnancy test should also be done if there has been any irregular spotting or bleeding between periods. Consider doing a pregnancy test every 4 weeks for any patient who does not have a consistent bleeding pattern (21-35 day cycles).
- ◆ ****If the participant's pregnancy test is positive, permanently discontinue the study medications and notify the Principal Investigator.** Pregnant women can continue to receive the counseling components of the treatment. In addition, refer the patient to an appropriate medical care provider regarding her pregnancy.

Year	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
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COMBINE Menstrual Calendar (MCA ver. A)

Center Participant # Participant Initials

mo.		da.		yr.				

Instructions: Complete at each MM visit as an extension of the SAFTEE. This form is cumulative.

Week # / Sequence #	MM Session Date (mm/dd/yy)	Birth Control		Type of birth control (see codes at bottom of page)	Date of 1 st day of last menstrual period (mm/dd/yy)	Pregnancy test		Pregnancy test Results		√ if entered in DMS
		Yes	No			Yes	No	Positive	Negative	
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[Answer at initial session only]

Was the woman's cycle regular (21-35 days)? ___Yes ___No If No, what is the length of the typical cycle? _____days

Methods of Birth Control: **1**=oral contraceptives **2**=hormonal (levonorgestrel) or surgical implants **3**=barrier plus spermicide **4**=abstinence **5**=Other **6**=N/A (menopausal-no period for > 1 year, hysterectomy, tubal ligation)