Use this worksheet to guide and document protocol adherence counseling, which encompasses protocol adherence, product use, and contraceptive counseling. Contraceptive counseling should begin at the screening visit, and protocol adherence and product use counseling should begin at the enrollment visit.

For all follow-up clinic visits (V2-10), all three components of protocol counseling must be provided and documented, but may be abbreviated and content tailored to participant needs. Protocol counseling is only if indicated at the Final Contact (V11). Staff should review the participant’s Protocol Counseling Worksheet from the previous visit to determine the level of counseling needed and issues to revisit.

**Protocol Adherence and Product Use Counseling**

[ ]  N/A (Protocol Adherence/Product Use Counseling not required at Screening Visit)

At enrollment, thoroughly review the Study Adherence Guidelines sheet and the Vaginal Ring Insertion Instructions/Important Information sheet with the participant and give her a copy to reference at home.

At enrollment and all follow-up visits, ask the participant if she has any questions and review any medications, non-study products, and practices that the participant should refrain from before the next visit. Offer a copy of the Study Adherence Guidelines at each visit.

[ ]  Study Adherence Guidelines reviewed and discussed

[ ]  Vaginal Ring Insertion Instructions/Important Information sheet reviewed and discussed

Any protocol adherence issues/questions/concerns discussed at this visit?

[ ]  None reported

[ ]  Yes. Describe discussion, indicated counseling provided, and note issues to follow-up at next visit:

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

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**Contraceptive Counseling**

[ ]  Check here if participant has undergone supracervical hysterectomy or bilateral oophorectomy and contraceptive counseling is not required. *If checked, end of form.*

At screening, review protocol contraception requirements as well as the participant’s current contraceptive method(s) and/or preferences, and any questions she may have.

At enrollment and all follow-up visits (2-9), ask the participant if she has any questions or concerns, confirm current contraceptive method(s), and ensure participant has adequate contraceptive coverage until her next visit.

Current contraceptive method: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this a change from the previous visit?

[ ]  N/A (Screening visit)

[ ]  No

[ ]  Yes. Explain change:

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

Status of next contraceptive prescription:

[ ]  N/A

[ ]  Prescription refill/renewal or injection needed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Date).

Any contraceptive information/issues/questions/ concerns discussed at this visit?

[ ]  No

[ ]  Yes. Describe discussion, indicated counseling provided, and note issues to follow-up at next visit:

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

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