Use this worksheet to guide and document protocol counseling, which encompasses the following components:

* Contraceptive counseling should begin at the screening visit (Required for CIS-females only)
* Protocol adherence counseling should begin at the enrollment visit
* Product use counseling should be provided as appropriate for each Dosing Visit (V3, 5 and 7).

For follow-up clinic visits (V2-8a), adherence and contraceptive counseling must be provided and documented, but may be abbreviated and content tailored to participant needs. Protocol Counseling is only conducted if indicated at the Final Contact (V9). 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**

At enrollment, thoroughly review the Study Adherence Guidelines sheet with the participant and give him/her a copy to reference at home. At all follow-up visits, ask the participant if he/she has any questions. Review the timing and content of the next visit and any medications, non-study products, and practices that the participant should refrain from before the next visit. Offer copies of the Study Adherence Guidelines for the participant to take home.

[ ]  Protocol Adherence Counseling not done (Not required at Screening Visit)

**or**

[ ]  Study Adherence Guidelines sheet reviewed and discussed

At each Dosing Visit (V3, 5, and 7), explain the study gel administration (amount and procedure) for that day. Reference the informed consent form, as needed, to guide this discussion. If V5 or V7, debrief with the participant on his/her previous product use experience(s). Address any questions or concerns the participant may have.

[ ]  Product Use Counseling not done (not provided at non-dosing visits)

**or**

[ ]  Study gel administration explained and discussed

Any protocol adherence or product use 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**

 **□** N/A (if not a cis-female participant)

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, 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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