Use this worksheet to guide and document protocol counseling, which encompasses protocol adherence counseling. At Screening, Enrollment and Visits 3-10, protocol adherence counseling must be provided; during follow-up, counseling may be abbreviated and tailored to participant needs. Staff should review the participant’s Protocol Counseling Worksheet from the previous visit to determine the level of counseling needed and any issues to revisit.

**Protocol Adherence Counseling:**

* **At Visits 1-10, provide guidance on study requirements, including prohibited practices, products and/or medications**
* Present to study visits as scheduled
* Abstain from the use of the following prohibited medications/products:
* Rectally-administered medications and products, including any containing N-9
* Anticoagulants or blood thinners \*\*
* Strong/moderate CYP3A inducers/inhibitors \*\*
* NSAIDs (nonsteroidal anti-inflammatory drugs) \*
* Aspirin (over 81 mg per day) \*
* PrEP (oral Truvada) \*\*
* PEP \*\*
* Abstain from the following prohibited activities 72 hours (3 days) ***prior to*** and ***following*** clinic visits:
* Receptive anal intercourse
* Receptive oral intercourse
* Receptive anal or genital stimulation
* Insertion of any non-study products or objects into the rectum, including:
	+ Fingers
	+ Rectal medications
	+ Enemas
	+ Lubricants
	+ Sex toys (such as dildos, anal plugs, etc.)
* Abstain from the following prohibited activities 72 hours (3 days) ***prior to*** clinic visits: □ N/A
* Receptive vaginal intercourse
* Insertion of any non-study products or objects into the vagina, including:
* Fingers
* Spermicides
* Vaginal medications (including hormones)
* Vaginal douches
* Lubricants or vaginal moisturizers
* Sex toys (such as vibrators, dildos, etc.)
* Abstain from using tampons within 24 hours prior to clinic visits □ N/A
* Inform study staff of any medications, vitamins, nutritional supplements and herbal preparations taken during study participation
* Do not take part in other research studies involving drugs, medical devices, vaccines or genital or rectal products for the duration of study participation
* Contact study staff with any questions and/or to report any study-related issues

\* *Within 72 hours* ***prior to*** *and* ***following*** *a tissue sample collection visit*

\*\* *Reported use of these medications will result in permanent discontinuation of study product and*

 *termination from the study.*

**Study Rectal Insert and Enema Counseling:**

* **At Visit 2 (Enrollment) and Visit 6 (72-hr Post-Dosing Visit):**
* Provide home enema kit and review kit contents
* Review enema preparation and administration instructions
* Encourage participant to ask any questions about the home enema and to inform staff of any issues with its use
* Instruct participant to return any unused enema kit supplies to the clinic
* Encourage participant to hydrate extensively the night before dosing visit and not consume food 8 hours prior to tissue biopsy collection
* **At Visit 3 (Dosing Visit 1) and Visit 7 (Dosing Visit 2):**
	+ Explain procedures around in-clinic enema provision
	+ Provide an overview of the study rectal insert
	+ Review rectal insert guide and, if applicable, provide a copy to participant
	+ Explain that study rectal insert doses will be administered by site staff in the study clinic
	+ Encourage the participant to ask any questions about the enema as well as the study rectal insert and administration procedures, and to inform staff of any issues with enema or insert administration
	+ **N/A**

**Any counseling issues/questions/concerns discussed at this visit?**

[ ]  None reported

[ ]  Yes. Document discussion, counseling provided, and issues to follow up on at next visit:

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

**Rectal Biopsies Counseling**

* **Group 1: At Visit 2 (Enrollment) and Visits 3, 5, 7 and 9:**
	+ **N/A**
* **Group 2: At Visit 2 (Enrollment) and Visits 4, 6, 8 and 10:**
	+ **N/A**
* Explain to participant that clinic staff will collect rectal tissue
* Explain the process for rectal tissue collection
* If there is any discomfort during the procedure, participant should immediately inform study staff

**Rectal and/or Vaginal Fluid Collection Counseling**

* **Group 1: At Visit 2 (Enrollment) and Visits 3, 5, 7 and 9:**
	+ **N/A**
* **Group 2: At Visit 2 (Enrollment) and Visits 3, 4, 6, 7, 8 and 10:**
	+ **N/A**
* Explain to participant that clinic staff will collect rectal fluid and, if applicable, vaginal fluid
* Explain the process for rectal/vaginal fluid collection
* If there is any discomfort during the procedure, participant should immediately inform study staff

**Contraceptive Counseling:**

 **□** N/A (if not of child bearing potential)

At Screening

* Review protocol contraception requirements
* Review participant’s current contraceptive method(s) and/or preferences (document below)
* Review contraceptive issues/questions/ concerns (document below)

At Enrollment and all follow-up visits if indicated:

* Ask participant if she has any questions or concerns
* Confirm current contraceptive method(s)
* 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:

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