**Instructions:** Protocol counseling is required at all in-person study visits or phone follow-up visits as needed. This page includes details of each type of counseling and is to be used as a guide to review the elements of protocol counseling required at each timepoint. Counseling will be provided by different site staff than those conducting the behavioral assessments.

**GENERAL PROTOCOL COUNSELING**

* Inform study staff of use of any prescription meds, OTC preparations, vitamins, nutritional or herbal supplements
* Adhere to all protocol requirements, including limitations on sexual/anal activity and vaginal/rectal product use during specific time periods during study; starts 48 hrs prior to enrollment visit, during daily dosing phase and approximately 10 days after cervicovaginal tissue sampling
  + Abstain from receptive (receiving) sex, includes vaginal, anal and oral sex
  + Refrain from using vaginal products, such as spermicides, lubricants, moisturizers, contraceptive vaginal rings, douches, vaginal medications including antibacterials, antifungals, tablets, gels, suppositories, hormones
  + Abstain from inserting anything in the vagina and/or rectum, including tampons, menstrual cups, pessaries, sex toys (vibrators, dildos, etc.), fingers, female condoms, diaphragms, cervical caps or any other vaginal barrier method, external creams, lotions, ointments, wipes etc**.**
* Do not participate in other research studies while enrolled in MATRIX-001
* Review importance of attending all study visits
* Schedule next visit/contact. Provide clinic contact card, as needed. Contact clinic if unable to make next visit
* Contact study staff if any issues or concerns arise during study participation
* Vaginal insert self- insertion visits (Visits 3, 5 and 6) should be scheduled when the participant is not having menses-like bleeding

**CONTRACEPTIVE COUNSELING**

* Contraceptive Counseling, for participants of childbearing potential

**HIV pre- and post-test counseling and HIV/STI RISK REDUCTION COUNSELING**

* Greet client, establish rapport; emphasize confidentiality; address immediate concerns or issues
* Document any participant issues and associated discussion; document understanding and next steps
* **HIV Education and Pre-Test Counseling**

|  |  |
| --- | --- |
| * Review difference between HIV and AIDS | * Review plan if today’s test shows possible infection |
| * Review modes of HIV transmission | * Review window period and how it may affect results |
| * Review methods of prevention | * Correct any misconceptions or myths |
| * Review HIV tests to be done today | * Verify readiness for testing |

* **HIV/STI Risk Reduction Counseling**

|  |  |
| --- | --- |
| * Use open-ended questions to assess risk factors | * Probe on factors associated with higher vs lower risk |
| * Have risk factors changed since last visit | * Discuss risk reduction strategies moving forward |

* **HIV Post-Test Counseling**

|  |  |
| --- | --- |
| * Provide and explain test results | * Assess client understanding of results/next steps |
| * Explain additional testing that may be required | * Provide additional counseling/referrals as needed |

**BIOPSY PROCEDURAL COUNSELING**

* Counseling participants at Visits 2, 4 and 7 for the collection of cervicovaginal tissue(s)
* Approximately 10 days after cervicovaginal tissue sampling
  + Abstain from receptive (receiving) sex, includes vaginal, anal and oral sex

* + Refrain from using vaginal products, such as spermicides, lubricants, moisturizers, contraceptive vaginal rings, douches, vaginal medications including antibacterials, antifungals, tablets, gels, suppositories, hormones
  + Abstain from inserting anything in the vagina and/or rectum, including tampons, menstrual cups, pessaries, sex toys (vibrators, dildos, etc.), fingers, female condoms, diaphragms, cervical caps or any other vaginal barrier method, external creams, lotions, ointments, wipes etc.

**STUDY PRODUCT COUNSELING**

* Provide and review IRB/IEC approved vaginal insert instructions (i.e. pamphlet and/or video)
* Encourage participant to ask any questions regarding vaginal insert
* Counsel participants that self-insertion will not be directly observed; staff will be available (i.e. directly outside room or behind curtain) if any questions arise during self-insertion
* Remind participants to ensure hands are clean and completely dry prior to handling/inserting vaginal insert
* Find comfortable position for self-insertion
* Use whichever fingers are most comfortable to hold the insert; place the insert 4-5 cm into vagina and remove finger
* If unsuccessful or issues arise with self-insertion, a clinician can check for placement and provide further instructions
* Encourage participant to inform staff of any issues with vaginal insert use during the study

**Instructions:** Use page one as a guide to review all elements of the required counseling at each visit below. Document counseling by entering initials after each element is completed. If any counseling item occurs outside of visit date, include date of counseling with initials. Note any issues/concerns as applicable to use as a guide for the next visit. Encourage participant to inform study staff if they have not been able to follow any of the guidelines.

**V1: SCREENING Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  |  |
| HIV PRE-TEST COUNSELING |  |  |
| HIV POST-TEST COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V2: ENROLLMENT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  |  |
| HIV PRE-TEST COUNSELING |  |  |
| HIV POST-TEST COUNSELING |  |  |
| BIOPSY PROCEDURAL COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V3: Randomization (1st Vaginal insert) Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  |  |
| HIV PRE-TEST COUNSELING |  |  |
| HIV POST-TEST COUNSELING |  |  |
| STUDY PRODUCT COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V4: 24hr post 3rd dose insert Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING (abbreviated, as applicable) |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| BIOPSY PROCEDURAL COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V5: Fourth dose insert Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING (abbreviated, as applicable) |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| STUDY PRODUCT COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V6: Fifth dose insert Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING (abbreviated, as applicable) |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| STUDY PRODUCT COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V7: 24/48/72-hours Post Last Dose Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| PROTOCOL COUNSELING (abbreviated, as applicable) |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  |  |
| HIV PRE-TEST COUNSELING |  |  |
| HIV POST-TEST COUNSELING |  |  |
| BIOPSY PROCEDURAL COUNSELING |  |  |
| OTHER: IDI component  Confirm permission to participate in IDI |  |  |
| OTHER: Offer male condoms |  |  |
| ADDITIONAL NOTES: | | |

**V8: Study Exit Visit (SEV) Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on page 1 | **Initials** | **Comments** |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  |  |
| HIV PRE-TEST COUNSELING |  |  |
| HIV POST-TEST COUNSELING |  |  |
| OTHER: Offer male condoms |  |  |
| OTHER: IDI component   * Confirm permission to participate in IDI |  |  |
| OTHER: Last scheduled in-person study visit   * Will no longer have access to services provided by study * Offer referral sheet for care or counseling as needed |  |  |
| ADDITIONAL NOTES: | | |