**Instructions:** Protocol counseling is required at all in-person study visits. This page includes details of each type of counseling and is to be used as a guide to review the elements of protocol counseling performed at each timepoint.

**PROTOCOL COUNSELING (AND PARTICIPANT REMINDERS)**

* Report use of any prescription meds, OTC preparations, vitamins, nutritional and/or herbal supplements
* Adhere to all protocol requirements, including limitations on sexual activity and vaginal product use in month 1
* Do not participate in other research studies while enrolled in MATRIX-002
* 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
* V2 (Enrollment) and subsequent clinic visits should be scheduled when not having menses-like bleeding

**CONTRACEPTIVE COUNSELING**

* Contraceptive Counseling, as per site/clinical standard and 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
 |

**“PELVIC REST” IN MONTH 1 COUNSELING**

* For approximately one month, starts after the first film is inserted up until V6, 4-week visit
	+ Abstain from receptive (receiving) sex, includes vaginal, anal and oral sex
* Refrain from using vaginal products or practices, such as spermicides, lubricants, moisturizers, contraceptive vaginal rings, douches, herbs or other internal cleansing practices, vaginal medications including antibacterials, antifungals, tablets, gels, suppositories, hormones
* Abstain from inserting anything in the vagina, including tampons, menstrual cups, pessaries, sex toys (vibrators, dildos, etc.), fingers, female condoms, diaphragms, cervical caps or any other vaginal barrier method, drying agents/substances etc.

**STUDY PRODUCT USE COUNSELING**

* Provide and review IRB/IEC approved vaginal film insertion instructions
* Encourage participant to ask any questions regarding vaginal film insertion
* Explain that self-insertion will not be directly observed; however, staff will be available (i.e. outside room or behind curtain) if any questions arise during self-insertion
* Wash and dry hands completely prior to handling/inserting film
* Find a comfortable position for self-insertion
* Participant may attempt insertion with two films; clinician will do assessment after each attempt to check placement
* If self-insertion is unsuccessful, a clinician will place the film using a speculum
* Four weeks after each film/at next in-person visit, any visible residual film will be removed
* Encourage participant to inform staff of any issues with vaginal film use during the study

**Instructions:** Ideally, protocol counseling should occur after the administration of behavioral assessments. 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 and complete PROTOCOL DEVIATION LOG. 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 |  |  |
| [ ]  “PELVIC REST” IN MONTH 1 COUNSELING |  |  |
| ADDITIONAL NOTES: |

**V2: ENROLLMENT (1ST FILM INSERTION) 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 USE COUNSELING |  |  |
| [ ]  “PELVIC REST” IN MONTH 1 COUNSELING |  |  |
| ADDITIONAL NOTES: |

**V4: 1-WEEK TELEPHONE CONTACT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Counseling** (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| [ ]  PROTOCOL COUNSELING |  |  |
| ADDITIONAL NOTES: |

**V5: 2-WEEK TELEPHONE CONTACT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Counseling** (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| [ ]  PROTOCOL COUNSELING |  |  |
| ADDITIONAL NOTES: |

**V6: 4 WEEK VISIT (2nd FILM INSERTION) 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 USE COUNSELING |  |  |
| [ ]  OTHER: No restrictions on sex or vaginal products |  |  |
| [ ]  OTHER: Sexual partner IDI component* Review and re-confirm consent decision
* Discuss details of sexual partner involvement, including how partner contact will be initiated per site SOP
 |  |  |
| ADDITIONAL NOTES: |

**V8: 6-WEEK TELEPHONE CONTACT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Counseling** (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| [ ]  PROTOCOL COUNSELING |  |  |
| ADDITIONAL NOTES: |

**V9: 8 WEEK VISIT (Final scheduled in-person visit) 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 |  |  |
| [ ]  OTHER: Sexual partner IDI component* Confirm permission to contact sexual partner for IDI subset, if applicable
* Invite per site Sexual Partner Contact SOP (i.e., collect partner contact information or provide site contact information)
 |  |  |
| [ ]  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: |