**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 for the first 14 days when using each ring and vaginal product use/practices for the duration of the study
* Do not participate in other research studies while enrolled in MATRIX-003
* 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 V6 should IDEALLY be scheduled when not having menses-like bleeding
* Encourage participant to inform staff of any issues with vaginal ring use during the study

**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 |

**VAGINAL ACTIVITY RESTRICTION/ABSTINENCE COUNSELING**

* Practice sexual abstinence for the first 14 days after each ring is inserted:
  + Abstain from vaginal intercourse, including oral, digital, and penile penetration
  + Abstain from inserting anything in the vagina, including fingers, toys, etc.
* There are no restrictions on penetrative vaginal sex during the second half (i.e. day 15 – 28) of each product use period
* Abstain from intravaginal product use and practices other than sex (e.g., vaginal steaming, insertion of herbal preparations) for the duration of the study, including medications, menstrual cups, tampons, and douches

**STUDY PRODUCT USE COUNSELING**

**Describing the IVR**

* Clinicians and staff should avoid describing the intravaginal rings to participants as “hard,” “soft,” or “plastic”; these terms may have negative connotations and create bias. Describing the IVR as “flexible” and the components to be pinched during insertion as “tabs” is accurate and anticipated to be neutral language.
* If participants ask about what the IVRs are made of, inform them that the IVRs are made from medical-grade materials commonly used in medical devices (such as joint replacements).
* If participants ask about the difference between the two intravaginal rings they will use, staff should let them know that there are slight differences in the flexibility of the material that are not expected to be noticeable.

**Insertion visit**

* Provide and review IRB/IEC approved *Intravaginal Ring Use Instructions*
* Encourage participant to ask any questions regarding vaginal ring 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 vaginal ring
  + *CLINICIAN REMINDER: Participant will open the ring in the presence of the clinician; clinician will visually inspect ring prior to insertion*
* Find a comfortable position for self-insertion
* Participant may attempt vaginal ring insertion twice; clinician will do assessment (digital exam) after each attempt to check placement
* If self-insertion is unsuccessful, a clinician will place the vaginal ring
* Encourage participant to walk around the room after placement to ensure there is no discomfort
* A digital exam may be repeated if necessary
* During first insertion visit
  + Encourage participant to attempt to remove, following the *Intravaginal Ring Use Instructions*. If successful, ask them to reinsert the ring.
  + If participant is uncomfortable with attempting removal and reinsertion, clinician should use best judgement about whether to further encourage them.
* Provide participants with the following information
  + Each ring will be left in place for approximately 4 weeks
  + If the ring falls out at home and is not contaminated, it may be rinsed with clean water and re-inserted; do not use soap or detergent to clean the ring. If the ring falls into the toilet, do not re-insert.
* A copy of the *Intravaginal Ring Use Instructions* will be given to the participant to take home along with a bag in case the ring falls out and is not able to be re-inserted (i.e. contaminated or participant unable to re-insert). Participants should bring the ring back to the clinic in the provided bag.
* Encourage participant to inform staff of any issues with vaginal ring use during the study.

**Removal visit**

* Provide and review IRB/IEC approved vaginal ring removal instructions included in *Intravaginal Ring Use Instructions*
* Encourage participant to ask any questions regarding vaginal ring removal
* Explain that self-removal will not be directly observed; however, staff will be available (i.e. outside room or behind curtain) if any questions arise during self-removal
* Wash and dry hands completely prior to attempting to remove vaginal ring
* Find a comfortable position for self-removal
* Participant may attempt vaginal ring removal twice
* If self-removal is unsuccessful, a clinician will remove the vaginal ring
  + *CLINICIAN REMINDER: Clinician will visually inspect ring prior to disposing*

**Instructions:** Ideally, protocol counseling should occur after the administration of behavioral assessments. Use pages one and two as a guide to review all elements of 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 pages 1 & 2 | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  |  |
| HIV/STI RISK REDUCTION COUNSELING |  |  |
| HIV PRE-TEST COUNSELING |  |  |
| HIV POST-TEST COUNSELING |  |  |
| VAGINAL ACTIVITY RESTRICTION/ABSTINENCE COUNSELING |  |  |
| ADDITIONAL NOTES: | | |

**V2: ENROLLMENT (1st RING INSERTION)**  **Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on pages 1 & 2 | **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 |  |  |
| VAGINAL ACTIVITY RESTRICTION/ABSTINENCE COUNSELING |  |  |
| ADDITIONAL NOTES: | | |

**V3: 1st RING DAY 7 TELEPHONE CONTACT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **If indicated Counseling** as detailed on pgs 1 & 2  (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  | N/A |
| HIV/STI RISK REDUCTION COUNSELING |  | N/A |
| ADDITIONAL NOTES: | | |

**V4: 1st RING DAY 14 CLINIC VISIT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on pages 1 & 2  (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  | N/A |
| HIV PRE-TEST COUNSELING |  | N/A |
| HIV POST-TEST COUNSELING |  | N/A |
| OTHER: No restrictions on sex or vaginal products |  |  |
| ADDITIONAL NOTES: | | |

**V5: 1st RING REMOVAL VISIT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on pages 1 & 2  (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  | N/A |
| HIV PRE-TEST COUNSELING |  | N/A |
| HIV POST-TEST COUNSELING |  | N/A |
| STUDY PRODUCT USE COUNSELING |  |  |
| SEXUAL PARTNER IDI COMPONENT   * Confirm permission to contact sexual partner for IDI subset, if applicable * Discuss details of sexual partner involvement, including how partner contact will be initiated per site SOP |  |  |
| ADDITIONAL NOTES: | | |

**V6: 2nd RING INSERTION VISIT**  **Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on pages 1 & 2 | **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 |  |  |
| VAGINAL ACTIVITY RESTRICTION/ABSTINENCE COUNSELING |  |  |
| ADDITIONAL NOTES: | | |

**V7: 2nd RING DAY 7 TELEPHONE CONTACT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **If indicated Counseling** as detailed on pgs 1 & 2  (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  | N/A |
| HIV/STI RISK REDUCTION COUNSELING |  | N/A |
| ADDITIONAL NOTES: | | |

**V8: 2nd RING DAY 14 CLINIC VISIT Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on pages 1 & 2  (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **Initials** | **Comments** |
| PROTOCOL COUNSELING |  |  |
| CONTRACEPTIVE COUNSELING |  | N/A or current method: |
| HIV/STI RISK REDUCTION COUNSELING |  | N/A |
| HIV PRE-TEST COUNSELING |  | N/A |
| HIV POST-TEST COUNSELING |  | N/A |
| OTHER: No restrictions on sex or vaginal products |  |  |
| ADDITIONAL NOTES: | | |

**V9: 2nd RING REMOVAL VISIT/SEV Visit Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Required Counseling** as detailed on pages 1 &2  (per protocol: if indicated and/or per local SOC; detail in notes below or enter “NA”) | **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: Sexual partner IDI component   * Confirm permission to contact sexual partner for IDI subset, if applicable * Discuss details of sexual partner involvement, including how partner contact will be initiated per site SOP * Invite per site Sexual Partner Contact SOP (i.e., collect partner contact information or provide site contact information) |  | N/A |
| 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: | | |