



MATRIX-002 Study-Specific Procedures (SSP) Manual

Section 10 – Counseling Considerations

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10 Introduction

This section contains guidance on the following types of counseling provided in MATRIX-002:

- HIV Pre-/Post-Test Counseling
- HIV/STI Risk Reduction Counseling
- Contraceptive Counseling
- Study Product Counseling
- Protocol Adherence Counseling

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, motivation, skills-building, and/or referrals. Because of this, specific content to cover, or skills to emphasize, are not standardized. Rather, the process for these discussions is to allow for appropriate tailoring and targeting to an individual participant’s needs.

All counseling, and referrals if needed, should be documented in participant study records. A Sample MATRIX-002 Protocol Counseling Guide and Worksheet can be found on the MATRIX-002 webpage under Study Documents (<https://www.matrix4prevention.org/activity-hubs/clinical-trials/matrix-002/matrix-002-study-documents>). This worksheet may be tailored for use at all sites. Proper documentation may also be achieved through use of alternate counseling worksheets, and/or chart notes.

10.1 HIV Pre-/Post-Test Counseling

HIV testing is required at V1 Screening, V2 Enrollment and V6 and V9. HIV pre-test and post-test counseling is required at each visit at which HIV testing is performed. HIV/STI Risk Reduction Counseling (included on the Counseling Guide and Worksheet mentioned above) provides a guide to the minimum requirements for HIV and risk reduction counseling sessions.

All HIV counseling should be provided in accordance with local counseling standards and according to the **site SOP detailing HIV/STI Risk Reduction Counseling and HIV Pre-/Post-Testing Counseling**. Study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithm in protocol Appendix II.

Participant-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results. Counselors should provide and explain test results in a private setting per site SOPs. Counselors should assess participant understanding of results and provide clarification and further information as necessary. Regardless of status, continued risk-reduction should be emphasized.

Information on interpretation of screening, enrollment, and follow-up test results is provided in Table 1 which can be referenced as needed when providing pre-test and post-test counseling.

Table 1: Interpretation of HIV Test Results per Protocol Appendix II Algorithm

Test	Test Result	Interpretation
Initial Rapid Test	negative	<u>HIV-uninfected</u> ; test results indicate that you are not infected with HIV.
	positive or indeterminate	<u>HIV status not clear</u> ; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. See Protocol Section 9.6: At screening/enrollment per protocol: not eligible for enrollment. After enrollment: permanently discontinue study product and all follow-up visits. Provide counseling, management, and/or referrals for care per site SOP and local standards of care.
HIV Confirmatory Test	positive	<u>HIV-infected</u> ; test results indicate that you are infected with HIV. Provide counseling, management, and/or referrals for care per site SOP and local standards of care.
	negative or indeterminate	Consult MATRIX-002 Protocol Team

10.2 HIV/STI Risk Reduction Counseling

Risk reduction counseling is required when HIV testing is done (V1 Screening, V2 Enrollment, Visit 6 and Visit 9) and should be performed according to the site SOP. Participant-centered approaches should be used when assessing participant HIV/STI risk and providing risk reduction counseling. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying their risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

Risk reduction counseling sessions should offer skills building to the participant when indicated, e.g., on how to use condoms, how to discuss sensitive issues with partners and other influential persons.

10.3 Contraceptive Counseling

Contraceptive counseling for participants of childbearing potential begins at the screening visit and is performed at V2, V6, V9 and if indicated at V4, V5 and V8. When performed at the Screening and

Enrollment visits, contraceptive counseling should be provided in the context of assessing study eligibility criteria.

Per MATRIX-002 inclusion criteria, persons of childbearing potential must be protected from pregnancy starting two weeks before Screening and continuing for the duration of study participation by an effective contraceptive method and as confirmed by site SOP. At visits when contraceptive counseling is provided, staff should explain which methods are acceptable for study purposes and emphasize that if the participant cannot commit to using one of the methods for the duration of study participation, the participant should not enroll in the study. If a participant's method changes during study participation, the site should consult the PSRT for guidance regarding continued study participation.

Correct and consistent condom use (for US site only) is defined as:

- Correct condom use = participant report of use of condoms according to package insert
- Consistent condom use = (100% of the time) with vaginal intercourse with a male partner starting at least two weeks prior to the Screening Visit
- Condoms should not contain spermicide during study participation; condoms without spermicide will be available to study participants during study participation if needed

Contraceptive counseling should be performed during follow-up visits/contacts as applicable per protocol.

Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on the MATRIX-002 protocol. All sites are encouraged, as able, to review/obtain medical records as part of their verification procedures for participant reported contraceptive methods.

Contraceptive counseling should be documented in participant study records. Staff members providing the contraceptive counseling may document details on the Counseling Guide and Worksheet, a site-specific counseling worksheet, or in chart notes.

10.4 Product Use Counseling

Administration of the vaginal films is by self-insertion at the clinic during V2 and V6. Participants will be provided instructions. The items in the MATRIX-002 Protocol Counseling Guide and Worksheet should be reviewed with the participant at applicable visits. Staff should take as much time as needed to ensure the participant is comfortable and that all questions or concerns have been addressed regarding film insertion. This discussion should be done at each study product insertion visit (V2 and V6) and documented on the Protocol Counseling Guide and Worksheet or in chart notes. Specific self-insertion instructions are detailed in SSP Section 5, Study Procedures.

10.5 Protocol Adherence Counseling

Protocol adherence counseling is required at V1 Screening, V2 Enrollment, V6 and V9.

Per protocol, participants should be counseled regarding "pelvic rest" for month 1 (or from the first vaginal film insertion to V6/4 Week Visit). The details regarding protocol adherence counseling can be found in the Sample MATRIX-002 Protocol Counseling Guide and Worksheet and should be reviewed with the participant at applicable visits. Each counseling session should be fully documented in the Protocol Counseling Guide and Worksheet and/or chart notes.