

MTN-017 Operational Guidance #01



Counseling Requirements

The purpose of this communication is to provide further information on the documentation requirements as it pertains to the provision of protocol specified risk reduction or protocol adherence counseling and product use instructions. Per protocol, product use instructions and protocol adherence counseling is required at Initiate and Mid Period visits. Risk reduction counseling is required at every scheduled study visit, with the exception of Initiate Period 2 and 3 visits.

Counseling worksheets have been developed and are available on the [MTN-017 Study Implementation Materials webpage](#) under 'Counseling Tools/Worksheets.' These worksheets serve as a tool to guide each counseling session and may serve as source documentation if designed and completed appropriately. Otherwise, counseling sessions may be documented in chart notes.

When documenting the counseling session, it is not necessary to transcribe the entire conversation; instead, it is expected that a short summary of the discussion will be documented on your source document for counseling. This applies to all counseling provided to participants. Good documentation will assist you whenever you need to refer to the participants' history.

Documentation of the risk reduction counseling session should focus on the following:

- Participant's stated concern(s) in regards to transmission/acquisition of HIV/STIs;
- Participant's potential HIV/STI exposures;
- Participant's previous attempts at reducing risk for HIV/STI transmission or acquisition;
- Participant's readiness, willingness or ability to make a change;
- Any negotiated incremental step(s) towards reducing HIV/STI risk;
- Any referrals or resources offered.

Documentation of the product use instruction counseling should focus on the following components:

- An overview of the de-briefing session with the participant on his/her experience using product for the first time
- If the participant had any issues or problems and how addressed by site staff
- Any supplemental information provided to or asked by the participant (such as was he/she able to swallow the pill/insert the applicator without issue, whether he/she had any difficulties or any concerns about swallowing or inserting product at home).

Documentation of protocol adherence counseling session should focus on the following components:

- An overview of the discussion
- Participant questions or concerns adhering to protocol requirements and how questions and/or concerns were addressed

Should you have any questions about this information, feel free to contact the MTN-017 Management Team (mtn017mgmt@mtnstopshiv.org).