

**MTN-017 Visit Checklists**  
**Overview of Checklists and Identification of Current Versions**

| Number | Title                        | Current Version | Version Date | Updates and Comments   |
|--------|------------------------------|-----------------|--------------|--|
| 01     | Screening                    | 1.1             | 22-Jul-13    | <ul style="list-style-type: none"> <li>• Updated header/page numbers to carry over to next page</li> <li>• Collection of HSV rectal swab was moved up to occur prior to the digital examination</li> <li>• Updated SSP reference error in item #20</li> </ul>  |
| 02     | Enrollment/Initiate Period 1 | 1.2             | 29-Jul-13    | <ul style="list-style-type: none"> <li>• Updated to revise the format for the blood volume of blood and tube types</li> <li>• Added the following text to item #10 <i>“Transcribe results onto Safety Laboratory Results CRF once available”</i></li> <li>• Added the following text to item #11 <i>“Transcribe results onto HIV Results CRF”</i></li> <li>• Replaced <i>“PTID-Name Link Log”</i> with <i>“Randomization Envelope Tracking Record”</i> in item #25</li> <li>• A <b>Note</b> was added to item #28 &amp; #29</li> </ul> |
| 03     | Mid-Period (Visits 3, 6, 9)  | 1.1             | 22-Jul-13    | <ul style="list-style-type: none"> <li>• Added the following text to item #11 <i>“Transcribe results onto Safety Laboratory Results CRF once available”</i></li> <li>• Updated SSP reference errors in</li> </ul>  |

Last Updated 9 August 2013

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|----|---|-----|-----------|--|
|    |   |     |           | <p>item #12</p> <ul style="list-style-type: none"> <li>Item #s 24-26 were re-arranged so that participant adherence counseling takes place after provision of product, product use and protocol adherence counseling</li> </ul>  |
| 04 | Initiate Period 2 & 3                             | 1.2 | 22-Jul-13 | <ul style="list-style-type: none"> <li>Updated to revise the format for the blood volume of blood and tube types</li> <li>A <b>Note</b> was added to item #22 &amp; #23</li> <li>Deleted PK Data Convergence Interview if indicated procedure from item #25</li> </ul>   |
| 05 | Period 1/2 End (Visits 4 & 7)                     | 1.1 | 22-Jul-13 | <ul style="list-style-type: none"> <li>Updated to revise the format for the blood volume of blood and tube types</li> <li>Added the following text to item #13 <i>“Transcribe results onto Safety Laboratory Results CRF once available”</i></li> <li>Added the following text to item #14 <i>“Offer HIV counseling and testing for partner(s)”</i></li> </ul> |
| 06 | Period 3 End/Final Clinic Visit/Early Termination | 1.1 | 22-Jul-13 | <ul style="list-style-type: none"> <li>Updated to revise the format for the blood volume of blood and tube types</li> <li>Added the following text to item #12 <i>“Offer HIV counseling and testing for partner(s)”</i></li> <li>Updated SSP reference errors in</li> </ul>  |

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|----|---|-----|-----------|---|
|    |   |     |           | item #13  |
| 07 | Rectal Exam Checklist – (Enrollment and Follow up)          | 1.1 | 22-Jul-13 | <ul style="list-style-type: none"> <li>Updated SSP reference errors throughout checklist</li> <li>Added the following text to item #9 <i>“Refer for/provide treatment if needed”</i></li> </ul> |
| 08 | Period 1 Follow Up Phone Calls                              | 1.1 | 22-Jul-13 | <ul style="list-style-type: none"> <li>Deleted instruction below procedures table from the Period 3 Phone Calls Checklist regarding ongoing AEs</li> </ul>                                      |
| 09 | Period 1 Follow Up Phone Calls - Rectal Biopsy/Fluid Subset | 1.1 | 22-Jul-13 | Deleted instruction below procedures tables regarding ongoing AEs   |
| 10 | Eligibility Criteria  | 1.0 | 29-Apr-13 | N/A   |