

**MTN-027 Study-Specific Procedures Manual**  
**Overview of Section Contents and Identification of Current Section Versions**

| Section Number | Section Title                                       | Version Number (s) | Version Date(s)                           | Comments   |
|----------------|---|--------------------|---|--|
| 1              | Introduction  | 1.0                | 15 May 2015                               |  |
| 2              | Documentation Requirements                          | 1.0<br>1.1         | 15 May 2015<br>15 Sep 2015                | <ul style="list-style-type: none"> <li>Version 1.1 updates: Clarified requirements and recommendations for Investigator Brochure (IB) storage</li> </ul>   |
| 3              | Accrual and Retention                               | 1.0                | 15 May 2015                               |  |
| 4              | Study Visit Procedures                              | 1.0                | 15 May 2015                               |  |
| 5              | Informed Consent                                    | 1.0                | 15 May 2015                               |  |
| 6              | Web Randomization                                   | 1.0<br>1.1<br>1.2  | 15 May 2015<br>15 Sep 2015<br>04 Nov 2015 | <ul style="list-style-type: none"> <li>Version 1.1 updates: Updated with guidance from CM#1 regarding converting randomization time to local time</li> <li>Version 1.2 updates: Updated to clarify the meaning of the Eligibility Checklist Date listed on the randomization confirmation notice</li> </ul>  |
| 7              | Study Product Considerations For Non-Pharmacy Staff | 1.0                | 15 May 2015                               |  |
| 8              | Clinical Considerations and Safety Monitoring       | 1.0<br>1.1         | 15 May 2015<br>15 Sep 2015                | <p>Version 1.1 updates:</p> <ul style="list-style-type: none"> <li>Clarified the intent of PEP/PrEP exclusion criteria</li> <li>Added guidance on documentation of pre-existing bleeding, infrequent bleeding, and chronic conditions</li> <li>Updated to include guidance on documentation of bleeding from cervical biopsy collection</li> <li>Expanded guidance on assessment of relationship to the study product</li> <li>Minor formatting and edits made throughout</li> </ul>   |
| 9              | Laboratory Considerations                           | 1.0<br>1.1<br>1.2  | 15 May 2015<br>6 Aug 2015<br>15 Sep 2015  | <p>Version 1.1 updates:</p> <ul style="list-style-type: none"> <li>Section 9.7.9 updated to reflect new storage requirements for used rings to be 2-8°C</li> <li>Minor clarifications on shipping and storage requirements were made in tables 9-2 and 9-4</li> </ul> <p>Version 1.2 updates:</p> <ul style="list-style-type: none"> <li>Added clarification about the timing of cervical and rectal ‘hour 0’ sample collections on Day 28 to Table 9-3</li> <li>Minor updates were made to Tables 9.2 and 9.3, as well as a few other format changes</li> </ul> |

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|----|---------------------------|------------|----------------------------|--|
| 10 | Counseling Considerations | 1.0        | 15 May 2015                |  |
| 11 | Behavioral Measures       | 1.0<br>1.1 | 15 May 2015<br>23 Sep 2015 | <ul style="list-style-type: none"> <li>Version 1.1 updates: Added guidance on how to conduct an IDI in the event Skype video is malfunctioning and troubleshooting is unsuccessful.</li> </ul> |
| 12 | Data Collection           | 1.0        | 15 May 2015                |  |
| 13 | Data Communiqués          | 1.0        | 15 May 2015                |  |
| 14 | Study Reporting Plan      | 1.0<br>1.1 | 15 May 2015<br>04 Nov 2015 | <p>Version 1.1 updates:</p> <ul style="list-style-type: none"> <li>Updated SDMC staff listing</li> <li>Updated purpose and components of missed visit reports</li> </ul>                       |