

Section 2. Protocol

As of the date of this section, protocol Version 1.0 (28 September 2011), Letter of Amendment #1 (7 November 2011), Letter of Amendment #2 (19 April 2012), and Clarification Memo #1 (7 August 2013), reflects current protocol specifications. These documents are available on the ASPIRE website, and should be printed and filed site essential documents. It is not necessary to also file copies of these documents in this manual. It is expected that sites operate under the version that is currently approved by the local ethics committee/institutional review board.

Further information on the content and required handling of protocol clarification memos, letters of amendment, and full amendments is available in Section 10.2 of the MTN Manual of Operations (<http://www.mtnstopshiv.org/node/187>).