

## 2. Protocol

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### 2.1 Overview of Section 2

The table below documents the history of the HPTN 083 protocol along with Clarification Memos, Letter of Amendments, and Full Amendments. These documents are considered Essential Documents. A copy of each document should be available to staff and a copy should be maintained in the central files.

<b>Document</b>	<b>Date</b>
<b>HPTN 083 Protocol, Version 1.0</b>	<b>2 February 2016</b>
• HPTN 083 Letter of Amendment #1	24 May 2016
• HPTN 083 Letter of Amendment #2	26 July 2016
• HPTN 083 Letter of Amendment # 3	10 November 2016
• Clarification Memo # 1	13 October 2017
• Clarification Memo # 2	19 October 2017
• HPTN 083 Letter of Amendment # 4	14 December 2016
<b>HPTN 083 Protocol, Version 2.0</b>	<b>25 July 2018</b>
<b>HPTN 083 Protocol, Version 3.0</b>	<b>31 October 2019</b>
• Clarification Memo # 1	10 February 2020

Note: Clarification Memos and Letters of Amendment are incorporated into subsequent full versions of the protocol. A Clarification Memo may also be incorporated into a subsequent Letter of Amendment.