

Section 2. Protocol

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The table below documents the history of the HPTN 083-01 protocol along with Clarification Memos (CMs), Letter of Amendments (LoAs), and Full Amendments. These documents are considered Essential Documents. A copy of each document must be available to staff and a copy must be maintained with study regulatory files.

Document	Date
HPTN 083-01 Protocol, Version 1.0	03 October 2019
HPTN 083-01 Protocol, Version 2.0	23 August 2020
HPTN 083-01 Protocol, Version 3.0	02 July 2021
HPTN 083-01 LoA #1 to Version 3.0	14 January 2022

Note: CMs and LoAs are incorporated into subsequent full versions of the protocol. A CM may also be incorporated into a subsequent LoA.