

Section 2. Protocol

2.1	Overview of Section 2	2-1
-----	-----------------------------	-----

2.1 Overview of Section 2

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

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