

Section 2. Protocol

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2.1 Overview of Section 2

The table below documents the history of the HPTN 084 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 084 Protocol, Version 1.0	2 March 2017
HPTN 084 CM#1 to Version 1.0	11 May 2017
HPTN 084 LoA#1 to Version 1.0	15 August 2017
HPTN 084 CM#2 to Version 1.0	26 September 2017
HPTN 084 LoA#2 to Version 1.0	24 January 2018
HPTN 084 LoA#3 to Version 1.0	31 May 2018
HPTN 084 CM#3 to Version 1.0	02 August 2019
HPTN 084 Protocol, Version 2.0	06 November 2019
HPTN 084 CM#1 to Version 2.0	22 January 2020
HPTN 084 LoA#1 to Version 2.0	23 June 2020
HPTN 084 LoA#2 to Version 2.0	10 September 2020
HPTN 084 CM#2 to Version 2.0	16 September 2020
HPTN 084 LoA#3 to Version 2.0	22 October 2020
HPTN 084 LoA#4 to Version 2.0	16 November 2020
HPTN 084 Protocol, Version 3.0 (OLE 1)	16 August 2021
HPTN 084 LoA#1 to Version 3.0	24 September 2021
HPTN 084 CM#1 to Version 3.0	07 December 2021
HPTN 084 LoA#2 to Version 3.0	03 February 2022
HPTN 084 LoA#3 to Version 3.0	14 March 2022
HPTN 084 CM#2 to Version 3.0	21 July 2022
HPTN 084 Protocol, Version 4.0 (OLE 2)	02 November 2022
HPTN 084 CM#1 to Version 4.0	24 February 2023

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