

**Clarification Memo #1 to:**

**Letter of Amendment (LoA) #1, dated 3 December 2020**

**to**

**HPTN 084-01:**

**Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females – A Sub-study of HPTN 084**

**Protocol Version 1.0, dated 14 October 2019**

**FINAL Clarification Memo (CM), dated 30 December 2020**

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Summary of Revisions and Rationale

1. Corrected a typographical error in the Dear Participant Letter portion (Appendix I) of LoA #1, dated 3 December 2020, to V1.0 of the HPTN 084-01 protocol.
  2. Amended the signatures portion of the Dear Participant Letter (Appendix I) of LoA #1, dated 3 December 2020), to V1.0 of the HPTN 084-01 protocol.
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**Implementation**

The procedures clarified in this memorandum have been approved by the Division of AIDS (DAIDS) Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 084-01 Protocol Clarification Memo (CM) #1 to LoA #1 of HPTN 084-01, Version 1.0 is not required by the sponsor; however, sites may submit the CM to the responsible IRBs for their information or as required by local context.

No change in the informed consent forms is necessitated by or included in this CM.

The modifications included in this CM will be incorporated into the next full protocol amendment. Text noted below by shaded **bold** text will be added and by shaded ~~strikethrough~~ text will be deleted.

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**Revision 1-Related Changes**

1. In the last paragraph of the Dear Participant Letter (Appendix I) portion of LoA #1 to V1.0 of Protocol HPTN 084-01, the following typographical error was corrected:

“Enrolling in this study, the HPTN 084-01 study, will help to increase our knowledge about how CAB LA works in adolescents, which is still an important question. Thank you for participating in HPTN 084-**01**.”

**Revision 2-Related Changes**

2. In the signatures portion of the Dear Participant Letter (Appendix I), the following language has been removed and added, so that sites can amend those text in the manner in which suits their context.

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**[Insert appropriate way to capture Parent/Guardian Name (print)]**

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**[Insert appropriate way to capture Parent/Guardian Signature and Date]**

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**[Insert appropriate way to capture Study Staff information Study Staff Conducting Consent Discussion (print)]**

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**[Insert appropriate way to capture Study Staff Signature and Date]**  
~~Study Staff Signature and Date~~

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**[Insert appropriate way to capture Witness Name (print)]**  
(As appropriate)

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**[Insert appropriate way to capture Witness Signature and Date]**