

Sample HPTN 084 Participant Letter/Information Sheet

PRINCIPAL INVESTIGATOR: [Insert PI Name/Affiliation]

Dear HPTN 084 Participants,

We promised to let you know about any new information. We want to let you know that the United States Food and Drug Administration FDA approved long acting cabotegravir injection (CAB LA shots) to prevent HIV in adults and adolescents (youths) who are at risk for HIV. The FDA gave full approval on 20 December 2021. The data collected during this study added to that approval. Thank you so very much for your important help in the fight against HIV!

Regulatory authorities in other parts of the world like *[insert name of your regulatory authority]* will also review the data. These groups approve new medicines. They will make their own decisions about CAB LA for HIV prevention. We will let you know if they approve CAB LA to prevent HIV.

Thank you again for participating in HPTN 084. You made a real difference to the lives of many people.

Sincerely,

[Insert name and contact information of Investigator of Record]

If you have read this letter, or had it read and explained to you, and understand the information, please sign your name, or make your mark below.

Participant Name (print)

Participant Signature and Date

Study Staff Conducting
Consent Discussion (print)

Study Staff Signature and Date

Witness Name (print)
(As appropriate)

Witness Signature and Date