HIV Prevention Trials Network

Clarification Memo # 1 to:

HPTN 083-01:

Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males – A sub-study of HPTN 083

DAIDS Study ID: 38654

Protocol Version 3.0, dated 2 July 2021

Date of Clarification Memo: 18 May 2023

The items clarified in this Clarification Memorandum (CM) have been approved by the DAIDS Medical Officer and are to be implemented immediately upon issuance. Institutional Review Boards/Ethics Committees (IRBs/ECs) approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/EC overseeing the study at their site for information. This CM is official HPTN 083-01 documentation and is effective immediately.

This CM and all related IRB/EC correspondence must be retained in the site regulatory file and in other pertinent files. Protocol registration approval is not required by DAIDS for CMs.

If the full HPTN 083-01 protocol is amended in the future, the changes in this CM will be incorporated into the next version.

Summary of Revisions and Rationale

1. Protocol roster changes

Deletions to the protocol text are indicated by strikethrough; additions are indicated in **bold**.

Revision 1: Protocol roster

Sybil Hosek, PhD Research Professor Center for Dissemination and Implementation Science University of Illinois at Chicago 818 S Wolcott Ave, SRH – 6th Floor Chicago, IL 60612 Email: shosek@uic.edu Sybil Hosek, PhD Clinical Psychologist/Director of Research Department of Psychiatry Stroger Hospital of Cook County 1900 W Polk Street, #854 Chicago, IL 60612 United States Phone: +001 312 864 8030 Fax: +001 312 864 9203 Email: shosek@cookcountyhhs.org

Hans M.L. Spiegel, MD, PhD, DTMH, FAAP **Medical Officer PMPRB/Prevention Sciences Program Pediatric Infectious Diseases Contractor, Kelly Government Solutions** NIH/NIAID/DAIDS 5601 Fishers Lane Room 8B51A Rockville, MD 20852 Phone: 240-292-4633 Email: hans.spiegel@nih.gov Adeola Adeyeye, MD, MPA Medical Officer Prevention Science Program DAIDS. NIAID. NIH Room 8B36 MSC 9831 5601 Fishers Lane Rockville, MD 20852-9831 United States Phone: +001 240 669 5005 Cell: +001 240 619 9365 Email: adeola.adeyeye@nih.gov

Franklin Yates, MD, MA Medical Officer Maternal and Pediatric Infectious Diseases Branch Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health **Department of Health and Human Services** 6710B Rockledge Dr., MSC 7002 Bethesda, MD 20892 Phone: 240.890.3679 Email: franklin.yates@nih.gov Bill G. Kapogiannis, MD Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) BG 6710B RM 2150 6710B Rockledge Dr. Bethesda, MD 20817 United States Phone: +001 301 402 0698 Fax: +001 301 480 3882 Email:

Jontraye Davis, MHA

Community Programs Associate II Science Facilitation, FHI 360 359 Blackwell Street, Suite 200 Durham, NC 27701 United States Phone: +001 919 544 7040, Ext. 11715 Email: jodavis@fhi360.org