**Letter of Amendment #2 for:**

# IMPAACT P1026s
# Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum

**Version 10.0, dated 2 February 2016**

**IND # 64,535**
**DAIDS ES # 10040**

**Letter of Amendment Date: 13 April 2018**

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***Information/Instructions to Study Sites from the Division of AIDS***

The information contained in this Letter of Amendment (LoA) affects the IMPAACT P1026s study and must be submitted to site Institutional Review Boards (IRBs) as soon as possible for their review and approval. Approval must also be obtained from site regulatory entities if applicable per the policies and procedures of the regulatory entities. All IRB and regulatory entity requirements must be followed.

Upon obtaining IRB approval and any other applicable regulatory entity approvals, each site should immediately begin implementing this LoA. After the IRB-approved updated site-specific informed consent form (ICF) is made available, all study participants still in follow-up must be re-consented at their next scheduled study visit, and all new participants must be consented using the updated site-specific ICF.

Sites are required to submit an LoA registration packet to the DAIDS Protocol Registration Office (DAIDS PRO) at the Regulatory Support Center (RSC). Sites will receive a registration notification for the LoA after the DAIDS PRO verifies that all required registration documents have been received and are complete. Sites should not await this notification before implementing this LoA.

Please file this LoA, all associated IRB and regulatory entity correspondence, and all correspondence with the DAIDS PRO in your essential documents files for IMPAACT P1026s. If the IMPAACT P1026s protocol is amended in the future, the contents of this LoA will be incorporated into the next version of the protocol.

**IMPAACT P1026s**
**Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum**

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## Letter of Amendment Signature Page

I will conduct this study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable US Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

_____ _____
Signature of Investigator of Record Date

_____
Name of Investigator of Record
(printed)

### *Summary of Modifications and Rationale*

The following modifications are included in this LoA:

1. Updates language regarding regulatory entities and drug companies supporting the study that may review study records: Per ICH GCP E6 4.8.10(n) and DAIDS requirements, it is mandatory that all DAIDS-sponsored and/or supported trials include language that informs participants that other US, local, and international regulatory entities may also review study records. Protocol Section 11.2 and the sample ICF have been updated accordingly. As noted in the instructions above, current study participants must be re-consented using the updated site-specific ICF.
2. Other minor updates, clarifications, and corrections have been incorporated.

### *Implementation*

Detailed modifications of the protocol text are shown below in general order of appearance in the protocol. Deletions in the protocol text are indicated by strikethrough, and additions are indicated in bold.

- Protocol Team Roster:

  Protocol Data Manager
  ~~Elise Tjaden, MPH~~ **Kayla Denson, PhD, MBA**
  Phone: 716-834-0900 x~~7272~~ 7211
  Email: ~~tjaden@fstrf.org~~ **denson@fstrf.org**

- Section 11.2, Subject Confidentiality:

  […] Clinical information will not be released without written permission of the subject, except as necessary, for **inspection,** monitoring**, and/or auditing during or after the conduct of the study by authorized representatives of the study sponsors and their contractual monitors, IMPAACT,** ~~by~~ the **U.S.** FDA, **site drug regulatory authorities, the site IRBs/ECs**, OHRP **and other applicable U,S., local, and international regulatory entities**. ~~the NIAID, or the local or national IRB or Ethics Committee.~~ **Data or information from the study may be shared with drug companies, who have agreements with the protocol team and or U.S. NIH, or regulatory entities, but individual participants will not be identified.**

- The changes noted below apply to Sample Consent Forms - Appendices VI-A, VI-B, VI-C and VI-D:

  WHAT ABOUT CONFIDENTIALITY?

  *For U.S. Sites,* 2nd paragraph:
  People who may review your/your baby's records include: the U.S. Food and Drug Administration (FDA) **and other U.S., local and international regulatory entities;** (insert Name of Site) IRB, National Institutes of Health (NIH), **drug companies supporting the study**, the Office for Human Research Protections **(OHRP),** study staff, and study monitors. Any publication of this study will not use your/your baby's name or identify you/your baby personally.

  *For sites outside the U.S,* 2nd paragraph:
  Your/your baby's records may be reviewed by the Ministry of Public Health in your country, the FDA **and other U.S., local and international regulatory entities**; the Office of Human Research Protections (OHRP), the NIH, (*insert name of site)* IRB, Ethics Committee (EC), **drug companies supporting the study,** study staff, and study monitors.