

Letter of Amendment #1 for:

IMPAACT P1101

Phase I/II Dose-finding, Safety, Tolerance and Pharmacokinetics Study of a Raltegravir-Containing Antiretroviral Therapy (ART) Regimen in HIV-infected and TB Co-infected Infants and Children

A Multicenter, International Trial of the
International Maternal Pediatric Adolescent AIDS
Clinical Trials Network (IMPAACT)

Protocol: Version 3.0, dated 24 April 2017

Letter of Amendment Date: 15 March 2018

NCT 01751568

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Version 3.0, dated 24 April 2017

DAIDS Document ID # 11831

IND # 77,787 Held By NIAID

Letter of Amendment Date: 15 March 2018

Information/Instructions to Study Sites from the Division of AIDS

The information contained in this Letter of Amendment (LoA) impacts the IMPAACT P1101 study, including the sample informed consent form (ICF), and must be submitted to site Institutional Review Boards and/or Ethics Committees (IRBs/ECs) 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/EC and regulatory entity requirements must be followed.

Upon receiving IRB/EC approval and any other applicable regulatory entity approvals, all sites should immediately begin implementing this LoA and using the updated ICFs. After all required approvals are obtained, the updated ICFs should be used for all new participants. In addition, all previously enrolled participants must reconsent to ongoing study participation using the updated site-specific ICF. Re-consenting should take place at each enrolled participant's next study visit after all required approvals are obtained.

Sites are required to submit a 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/EC and regulatory entity correspondence, and all correspondence with the DAIDS PRO in your essential documents files for P1101. If the P1101 protocol is amended in the future, the contents of this LoA will be incorporated into the next version of the protocol.

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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

This LoA updates language regarding regulatory entities 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 10.2 and the sample ICF have been updated accordingly.

Implementation

The modifications included in this LoA are listed below in order of appearance in the protocol. Additions to the text are indicated in **bold**; deletions are indicated by ~~strike through~~.

In Section 10.2, Participant Confidentiality:

All laboratory specimens, evaluation forms, reports, and other records will be identified only by a coded number to maintain participant confidentiality. All records will be kept in a secured area. All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by the study staff, study monitors, FDA, the OHRP, NIH, the local IRB/EC, ~~or~~ Merck & Co., Inc, **and other US, local, and international regulatory entities.**

In Appendix VI, Sample Informed Consent Form for Study Participation, WHAT ABOUT CONFIDENTIALITY?, second paragraph:

Your child's records may be reviewed by the U.S. Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), (insert name of site) IRB/EC, National Institutes of Health (NIH), study staff, study monitors, ~~and~~ Merck & Co., Inc. (the drug company supporting this study), **and other US, local, and international regulatory entities.**