ACTG Network Coordinating Center

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LETTER OF AMENDMENT

DATE: August 22, 2018

TO: ACTG CTU Principal Investigators, CRS Leaders, and CTU/CRS Coordinators

FROM: A5324 Protocol Team

SUBJECT: Letter of Amendment #3 for Protocol A5324, Version 2.0, 08/25/17, entitled "A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV"

The following information impacts the A5324 study and must be forwarded to your institutional review board (IRB)/ethics committee (EC) as soon as possible for their information and review.

The following information also impacts the Sample Informed Consent. Your IRB/EC is responsible for determining the process of informing participants of the contents of this LOA.

Sites are still required to submit an LOA registration packet to the Division of AIDS (DAIDS) Protocol Registration Office (PRO) at the Regulatory Support Center. Sites will receive a registration notification for the LOA once the DAIDS PRO verifies that all required LOA registration documents have been received and are complete. An LOA registration notification from the DAIDS PRO is not required prior to implementing the LOA. A copy of the LOA registration notification, along with this letter and any IRB/EC correspondence, should be retained in the site's regulatory files.

The main reason for this LOA is to correct discrepancies in the Sample Informed Consent about pregnancy testing after study entry to be consistent with the pregnancy testing requirement that was updated through LOA #2. The corrections made to A5324, Version 2.0, 08/25/17, Sample Informed Consent, are explained below.

1. Appendix I, Sample Informed Consent, WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?:

   In the <u>After Entry</u> sub-section, seventh bullet, the following changes have been made:

   - If you are a woman ~~and you think you might be~~ **who can become** pregnant, you will have a pregnancy test **at every study visit**. You will be told the result of this test when it becomes available.

   In the <u>If You Have to Stop Taking the Study Drugs Early or You Have to Stop the Study Early</u> sub-section, fifth bullet, the following changes have been made:

   - If you are a woman ~~and you think you might be~~ **who can become** pregnant, you will have a pregnancy test. We will tell you the test result when it becomes available.

2. Per a new regulatory requirement by DAIDS, a Protocol Signature Page (PSP) is appended for submission to DAIDS Protocol Registration System (DPRS) as part of the LOA registration packet.

The information above will be incorporated into the next protocol version as necessary if the protocol is amended.

A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV
Version 2.0, 08/25/17

SIGNATURE PAGE

I will conduct the 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 U.S. 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.

Principal Investigator: _____
Print/Type

Signed: _____ Date: _____
Name/Title