

Letter of Amendment # 5 to:

**HPTN 069: A Phase II Randomized, Double-Blind, Study of the Safety and Tolerability of Maraviroc (MVC), Maraviroc + Emtricitibine (MVC+FTC), Maraviroc + Tenofovir disoproxil fumarate (MVC+TDF), or Tenofovir disoproxil fumarate + Emtricitibine (TDF+FTC) for Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission in At-Risk Men Who Have Sex with Men and in At-Risk Women, Version 3.0, January 3, 2013, DAIDS Document ID: 11789  
IND # 113,655**

**FINAL Version of LoA # 5: 24 February 2015**

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The following information impacts the HPTN 069 study and must be forwarded to all responsible Institutional Review Boards (IRBs) as soon as possible for their information and review. This Letter of Amendment must be approved by all responsible IRBs before implementation.

The change being made does not impact the sample informed consent forms, and the benefit-to-risk ratio for participants is not affected in any way.

Upon receiving final IRB and any other applicable Regulatory Entity (RE) approval(s) for this LoA, sites should implement the LoA immediately. Sites are still required to submit an LoA registration packet to the DAIDS Protocol Registration Office (PRO) at the Regulatory Support Center (RSC). Sites will receive a registration notification for the LoA once the DAIDS PRO verifies that all the 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 correspondence should be retained in the site's regulatory files.

If the HPTN 069 protocol is amended in the future, this Letter of Amendment will be incorporated into the next version. Text appearing below in highlighted **strike-through** will be deleted.

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**Summary of Revisions and Rationale**

The sponsor of the study, Division of AIDS/NIAID/NIH, on 06 February 2015 released an updated table to grade toxicities that occur in their sponsored studies. However, the previous grading table (Version 1.0, dated December 2004, clarification August 2009) will continue to be used for remainder of follow-up for HPTN 069 and the updated table, Version 2.0, dated November 2014, **will not** be used for this study. Continued use of Version 1.0 of the grading tables allows for continuity of reported adverse events throughout the lifespan of the trial. Section 6.4.3 is modified to clarify that the use of the previous grading table (Version 1.0, dated December 2004, clarification August 2009) will continue.

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**IMPLEMENTATION**

Section 6.4.3: Grading Severity of Events

The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, December 2004, clarification August 2009 ~~(or latest version)~~ must be used for determining and reporting the severity of adverse events. The DAIDS grading table is available on the DAIDS RSC website at <http://rsc.tech-res.com/safetyandpharmacovigilance>.