

**Notification of Change to:  
HPTN 052 Study-Specific Procedure (SSP) Manual, V 1.6**

**Attention:** HPTN 052 Investigators of Record, Study Coordinators, and site teams

**Subject:** Addition of Ritonavir to Study Product  
and  
Use of LPV/r for Breastfeeding and Ritonavir for Boosting ATV in Second Line Therapy

**Date:** 24 August 2009

This Notification of Change clarifies references to:

- Study Product (Section 8.2)
- Use of LPV/R and ritonavir received from CRPMC (Section 8.3.1)

Note that a ~~strikethrough~~ indicates deletions and **bold** indicates additions.

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Section 8.2 Study Product - (page 8-1):

HPTN 052 study product refers to ALL antiretroviral provided by the study. The antiretrovirals provided by the study include lamivudine 300mg (3TC, Epivir®), tenofovir disoproxil fumarate 300mg (TDF, Viread®), lamivudine 150mg/zidovudine 300mg (3TC/ZDV, Combivir®), nevirapine 200mg (NVP, Viramune®), efavirenz 600mg (EFV, Sustiva®, Stocrin®), atazanavir (ATV, Reyataz®), didanosine delayed-release capsules (ddI-EC, Videx EC®), stavudine (d4T, Zerit®), lopinavir/ritonavir (LPV/r, Kaletra®/Aluvia®), **ritonavir (r, Norvir®)**, and emtricitabine/tenofovir (FTC/TDF, Truvada® ).

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Section 8.3.1 Procedures for Ordering and Receiving Study Product from the CRPMC - (page 8-1):

3TC, TDF, 3TC/ZDV, ATV, NVP, EFV, ddI-EC, d4T, FTC/TDF, r, and LPV/r are available through the NIAID Clinical Research Products Management Center (CRPMC). An LPV/r-(Kaletra®/Aluvia®-) based regimen is the preferred regimen for women to receive if they become **or are enrolled while pregnant and when they are breastfeeding during ~~while enrolled in~~** the study; however, please note that LPV/r supplies are being donated only for these women **under these circumstances** and not for other purposes such as toxicity management or drug resistance. Sites are asked to use this drug only for treatment during pregnancy **and breastfeeding. In addition, only enough ritonavir (r, Norvir®) has been donated to the study to boost ATV in second-line therapy; therefore, it can only be used in this situation. If site-supplied Norvir (only Abbott-branded ritonavir) is available, sites may use it per their study physicians' discretion.** Site pharmacists are expected to order LPV/r and r Norvir® accordingly.