

Clarification Memo #2 to:

HPTN 052: A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples Version 3.0, November 20, 2006

Final Version: 31 August 2011

Summary of Revisions and Rationale

1.

Implementation

The procedures clarified in this memorandum have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB approval of HPTN 052 Protocol Clarification Memorandum #2 to HPTN 052 V. 3.0 is not required by the sponsor; however, sites may submit the clarification memo to the responsible IRBs/ECs for their information.

No change in the informed consent forms is necessitated by or included in this Clarification Memo.

The modifications included in this Clarification Memo will be incorporated into the next full protocol amendment. Text noted below by strikethrough will be deleted; text appearing below in **bold** will be added.

Revision 1 Table 3: Antiretroviral Therapies

Atazanavir ATV Reyataz®	PI	150 mg and 200 mg capsules	400 mg alone OR 300 mg if boosted with ritonavir**	2 PO QD with light meal or snack	25°C (77°F). Excursions permitted between 15°-30°C (59°-86°F)	ddI-EC should be taken on an empty stomach 1 hour before or 2 hours after ATV is taken with food. If ATV and TDF are used together, ATV should be boosted with RTV.
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**** As noted in Table 3 of HPTN 052 Final Version 3.0, 20 November 2006, ritonavir is used in this study to boost Atazanavir. Both ritonavir softgel capsules and tablets are available for this study.**