

**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: Target and Allowable Visit Windows

Date: 4 February 2009

This Notification of Change clarifies references to target and allowable windows in the HPTN 052 Study-Specific Procedure (SSP) Manual, V. 1.6. Note that a ~~strikethrough~~ indicates deletions and **bold** indicates additions.

Section 5.7.1 – page 5-9 (last sentence of paragraph following the table):

“The week 2 allowable window is -3/+3 days from the target visit date; the monthly allowable window is -7/+22 days from the target visit date; and the quarterly and yearly ~~target~~ **allowable** window is -7/+59 days from the target visit date.”

Section 11.5.2 – page 11-11 Target and Allowable Visit Windows:

A *target* visit window is the window within which a required visit should be completed. The target window for the Week 2 visit is -3 or +3 days from the target visit date. The target window for the monthly, quarterly, and yearly visits is -7 or +7 days from the target visit date.

An *allowable* window is a wider window to allow for situations where required visits cannot be done within the target window. As a result of LOA #3, the allowable windows for required visits have been revised as follows: Week 2 allowable window is -3/+3 days from the target visit date; monthly allowable window is -7 /+22 days from the target visit date; quarterly and yearly ~~target~~ **allowable** window is -7/+59 days from the target visit date.

Following is a table illustrating the first year’s target and allowable windows for those on the *immediate arm*:

Visit Type	Target Day	Target Window	Allowable window
Enrollment	Day 0	none	Day 0 – Day 7
Week 2	Day 14	Day 11 – Day 17	Day 11 – Day 17
Month 1	Day 30	Day 23 – Day 37	Day 23 – Day 52

Month 2	Day 60	Day 53 – Day 67	Day 53 – Day 82
Month 3 (Quarterly)	Day 90	Day 83 – Day 97	Day 83 – Day 149
Month 6 (Quarterly)	Day 180	Day 173 – Day 202-187	Day 173 – Day 239
Month 9 (Quarterly)	Day 270	Day 263 – Day 292-277	Day 263 – Day 329
Month 12 (Yearly)	Day 360	Day 353 – Day 382-367	Day 353 – Day 419

Following is a table illustrating the first year’s target and allowable windows for a *delay arm* participant. In this example, the participant initiates ART at the month 6 visit, but this can occur at any time during follow-up.

Visit Type	Target Day	Target Window	Allowable window
Enrollment	Day 0	none	None
Month 1	Day 30	Day 23 – Day 37	Day 23 – Day 52
Month 2	Day 60	Day 53 – Day 67	Day 53 – Day 82
Month 3 (Quarterly)	Day 90	Day 83 – Day 97	Day 83 – Day 149
Month 6 (Quarterly) (<i>ART initiation visit</i>)	Day 180	Day 173 – Day 202-187	Day 173 – Day 239*
Week 2	Day 194	Day 191 – Day 197	Day 191 – Day 197*
Month 7	Day 210	Day 203 – Day 217	Day 203 – Day 232*
Month 8	Day 240	Day 233 – Day 247	Day 233 – Day 262
Month 9 (Quarterly)	Day 270	Day 263 – Day 292-277	Day 263 – Day 329
Month 12 (Yearly)	Day 360	Day 353 – Day 382-367	Day 353 – Day 419

* Because the allowable window for quarterly and yearly visits is wide, you will encounter some overlap of allowable windows when a participant initiates ART. If the actual visit date for ART initiation occurs near the end of the allowable window, contact SCHARP to ensure the correct visit codes are used for the week 2 and monthly follow-up visits.