

HPTN 057 “Pausing” Procedures
11 January, 2007

- I. If any Grade 5 event (death) occurs that is deemed to be *definitely, probably, possibly or probably not* related to drug:
 - a. PSRT is notified (via the site or SCHARP Clinical Affairs) and convenes via call or email to review the event and determine next steps
 - b. If the PSRT decides to stop enrollment and study drug dosing at all sites while they are collecting more information, SCHARP will notify the study sites of this decision
 - c. SCHARP will notify the site of the PSRT’s final decision (to “pause” or to “continue as is”)

- II. If any Grade 4 AE or two of the same Grade 3 AEs (in different ptids) occur that are deemed *definitely, probably or possibly related* to drug:
 - a. Site manages participant as per protocol (Section 4.6.1)
 - b. PSRT is notified (via the site or SCHARP Clinical Affairs) and convenes via call or email to review the event and determine next steps
 - c. If the PSRT decides to stop enrollment and study drug dosing at all sites while they are collecting more information, SCHARP will notify the study sites of this decision
 - d. SCHARP will notify the site of the PSRT’s final decision (to “pause” or to “continue as is”)

Please note: Per the HPTN 057 Protocol and Letter of Amendment #1, sites are not to pause enrollment or study drug dosing until advised by the PSRT.