



MTN-032 Operational Guidance #1: Individual Drug Level Results Visual Tool

The purpose of this guidance document is to provide supplemental information regarding the distribution and management of the Individual Drug Level Results Visual Tool for study sites.

Individual Drug Level Results Visual Tool

Sites will be mailed a set of individual drug level results tools, labelled by ASPIRE PTID, for each pre-selected participant on recruitment lists. These tools are considered study documents and must be kept secure and confidential.

When a participant is enrolled, her AHA PTID must be written on the tool in the appropriate boxes.

During interviews, interviewers may annotate the visual tools with notes or information provided by the participant.

The tool should be scanned, uploaded to the FTP server and sent to RTI with the participant's debrief report, and then stored in the participant file.

Tools for former ASPIRE participants who do not enroll into MTN-032 should be stored at the site until the end of the accrual period, and then destroyed.

SSP Section 5 provides further instructions on using the tool. Additional questions may be directed to the MTN-032 Management team (mtn032mgmt@mtnstopshiv.org) or Ariana Katz (awkatz@rti.org).

All Operational Guidance documents must be printed and filed with regulatory documentation