



MTN-032 Operational Guidance #4: Male Partner Considerations, Phase 2 Accrual Reporting, and Recording Uploads

The purpose of this guidance document is to: **1)** Suggest ways that staff might provide male partners with HOPE study background information, as needed, during Phase 2; **2)** Add further details regarding probing on question 5 of the Male Partner FGD and IDI Guide; **3)** Outline the procedure for Phase 2 accrual reporting; and **4)** Stipulate a change in requirements for uploading interview recordings. Guidance contained in this document will be included in upcoming SSP revisions.

1) Provision of HOPE study background information to male partners

- a. If needed to further explain the dapivirine vaginal ring placement within the vagina, study staff can utilize the site's pelvic models. Pelvic models should be readily available during male partner FGDs and IDIs for this purpose.
- b. If site staff believe some or all male partners do not know the basics of the HOPE study and vaginal ring, site staff can provide a brief informal overview of the study and the ring prior to data collection.

2) Male Partner FGD and IDI Guide probing about study knowledge and information

The second probe under question 5 on the male partner FGD and IDI guides asks: "*How did you learn that information (e.g. male partner engagement activities, partner, study staff)? When did you learn it?*". If information has been provided to male partners by staff as outlined in Item 1 above, interviewers should ensure they probe on what male partners knew about the study *prior* to their involvement with MTN-032.

3) Phase 2 Accrual Reporting

Accrual reporting for Phase 2 of the study will be carried out using the SCHARP recruitment lists provided through the Atlas Website. For further information on completing the Recruitment List, refer to Protocol Version 2.0 training slides available on the MTN-032 website.

Once sites begin accrual for Phase 2, updated recruitment lists including accrual information should be sent to the MTN-032 Management Team at mtn032mgmt@mtnstopshiv.org by close of business each Friday. If no accruals have occurred during the week, or if a delay in reporting is expected, sites should send a message stating this to the management team in lieu of sending an updated report.

4) Uploads of Audio Recordings

- a. For Phase 2, sites are not required to upload audio recordings of IDIs or FGDs to the FTP server. Sites should not upload any audio recordings during the course of MTN-032 Phase 2. Instead, recordings should be maintained on-site as outlined in SSP Section 7.

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