



MTN-032 Operational Guidance #2: Recruitment Lists and Prioritization of Accrual Targets

The purpose of this guidance document is to provide supplemental information regarding the implementation and management of the MTN-032 site-specific Recruitment Lists, and the prioritization of the participant sub-groups and accrual targets.

Instructions for MTN-032 Recruitment Lists and Prioritization of Accrual Targets

The MTN-032 Recruitment List (RL) provides sites with the pre-selected former MTN-020 participant ID numbers (PTID) for recruitment into the MTN-032 study, and was sent as a single, password-protected, Excel document. These MTN-020 PTIDs are pre-selected by SCHARP based on the eligibility criteria per Section 5 of the MTN-032 protocol. MTN-032 SSP Manual Section 3 provides detailed information and the accrual targets for each sub-group of Phase 1:

Participant Group	~Total No. of Participants/Site for IDI	~Total no. of participants/site for FGD
Age 18-21		8
High level of drug detected	3	
Low level of drug detected	5	
Age 22-45		8
High level of drug detected	3	
Low level of drug detected	5	

The following description provides an outline of how the MTN-032 Recruitment Lists should be implemented to meet the stated accrual targets.

All pre-selected FGD participants are listed in the FGD tab of the Excel document, separated into the following sub-groups:

- Age 18-21
- Age 22-45

All pre-selected IDI participants are listed in the IDI tab, separate into the following sub-groups:

- Age 18-21, low drug detection
- Age 18-21, high drug detection
- Age 22-45, low drug detection
- Age 22-45, high drug detection

Per MTN-032 SSP Section 3, sites are to recruit participants in sequential order of each sub-group. It is recommended that sites recruit and conduct a few participants assigned to IDI first, as conducting a FGD is more complicated. In general, the younger IDI should be prioritized for enrollment into MTN-032.

For sites with too few participants pre-selected in the younger IDI sub-group to complete the accrual target for IDI, sites may prioritize conducting a few IDIs with the older IDI participants. These sites should then prioritize the younger sub-group as follows:

- 1) Prioritize recruiting for the younger age FGD first;
- 2) Recruit those who do not or cannot participate in the FGD for an IDI (due to scheduling conflicts, the younger FGD target being filled, or another reason); and
- 3) Notify the MTN-032 Management Team of this change in interview assignment and document the outcome on the RL and/or the Screening and Enrollment Log.

If there are inadequate numbers of pre-selected individuals on the RL for any of the other target sub-groups, sites should contact the MTN-032 Management Team for guidance on how to fulfill targets. Any other changes to interview modality assignment or subgroup targets must first be approved by the MTN-032 Management Team.

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