

MTN-034/REACH Study Qualitative Operational Guidance #01: Administration of Late Focus Group Discussions (LFGDs)

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This operational guidance document applies to the qualitative component at all REACH study sites. The purpose of this memo is to provide guidance to sites on how to proceed with conducting the LFGDs scheduled between Week 60/visit 20 and Week 76/visit 24. This operational guidance serves as approval from the Qualitative Management Team (QMT) to resume the scheduling of LFGDs as long as it is possible to do so while following national, site and/or IRB guidelines. In cases where national and/or site restrictions preclude the conduct of an in-person group meeting such as focus group discussions (FGDs), sites should contact the QMT.

In the monthly qualitative meetings, qualitative site staff and the RTI study coordinator will discuss the list provided by SCHARP that identifies participants eligible to take part in the LFGDs. The sites and RTI study coordinator will then select a number of participants to invite for the FGD. The MTN-034 Study-Specific Procedures (SSP) Manual Section 11.3.1.1 states that 6 to 8 participants should be invited to take part in the FGD. If fewer than 4 participants show up, the FGD should either be canceled or rescheduled. Due to COVID-19 and the need to meet public health guidelines on social distancing, the QMT suggests the following changes to the process of conducting LFGDs:

1. The target number of participants per LFGD is 4 to 6 participants, rather than the 6 to 8 participants as stated in the SSP Manual. Sites should ensure the venue is large enough to accommodate the number of invited participants, and that there is an adequate number of audio recorders to ensure sufficient audio quality for transcribing.
 - a. The reduced number of targeted participants is to allow for a minimum 2-meter distance between LFGD participants, while making sure that audio recorders can still pick up voices from all speakers.
 - b. Sites should discuss the best strategy for inviting these participants. Although we have encouraged inviting more participants than necessary previously, with the understanding that many will not show up, we understand that this strategy may need to be updated to better align with each site's COVID-related precautions.
2. If 2 to 3 participants show up, sites should still hold the FGD (group discussion).
3. If only 1 participant shows up for the scheduled FGD, rather than sending the participant away, sites should conduct an IDI with the single participant, if she is willing. Sites should still use the LFGD guide to conduct the interview. The interview should be documented in the QPL along with CIDs, and the corresponding materials will follow the same documentation and management procedures as CIDs. In the case where this scenario leads to a site exceeding the number of allowed CIDs, a Note to File will be written to explain why this occurred.
 - a. All the questions in the guide should be rephrased as appropriate for a single person interview rather than a group discussion.
 - b. At question #7, the point where the Statement Card game is supposed to take place, the interviewer should make all the statements into close-ended questions. For example, the interviewer should say, "do you agree, partially agree, or disagree with the following statement: REACH taught me skills and strategies that helped me stay adherent?" After

- each statement, the interviewer should then have a discussion with the participant about her response, probing about why she chose that option.
- c. At the completion of the IDI, sites should email the QMT to inform them of the change.

NOTE: The special case IDI is not meant to replace the LFGD and therefore, sites should reschedule the missed LFGD for another time (excluding the participant who took part in the special case IDI).

Please note that this Qualitative Operational Guidance is official study documentation and it should be filed as part of Essential Documents.



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Date