



## MTN-042 Operational Guidance #09: Update to Special Case IDI Selection Criteria

This operational guidance document updates the selection criteria for special case IDIs in Cohort 3.

For cohort 3, the EPDS is administered at the Enrollment visit, 4-week visit that corresponds with or is following 30 weeks gestation (i.e., at 30, 31, 32 or 33 weeks gestation), 6-week PPO visit, and at any time if indicated.

Per SSP section 14.3.3 (Study Accrual Plan and Site-Specific Accrual Targets - Cohort 3):

Special case interviews are not required. However, approximately ten special case interviews across all sites (identified by the site team and agreed upon by qualitative management team) may be invited (i.e., 10 total special case IDIs across sites for Cohort 3). Special case participants represent those with high EPDS scores at enrollment and/or interesting experiences related to behavioral endpoints (e.g., individuals who experience frequent VR expulsions or reported a social harm). Special case IDIs will not replace target numbers for purposefully selected IDIs based on parity.

**The underlined text is being expanded to include participants with high EPDS scores *at any point prior to their study exit visit (6-week PPO)*.** Individuals with a high EPDS score at the 6-week PPO visit will not be considered since there would not be an opportunity to complete the IDI prior to their exit from the study.

All Operational Guidance documents must be printed and filed with study essential documents.

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Marie Stoner, RTI Qualitative Research Coordinator

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