Section 3: Accrual, Eligibility Determination and Study Procedures

3. Introduction

MTN-045 will enroll heterosexual couples who have been in a relationship for ≥ 3 months (living together or not) and are interested in contraception and/or HIV prevention. The purpose of this SSP Manual section is twofold: 1) to provide information on requirements and procedures for recruiting participants and determining participant eligibility and 2) to outline study procedures for MTN-045.

3.1 Study Accrual Plan and SOP

Participants will be recruited from the communities served by the selected clinical research sites. Recruitment materials must be approved by site Institutional Review Boards/Ethics Committees (IRBs/ECs) prior to use. Site community representatives will advise on these materials before they are submitted to the IRB/EC for review. Community education strategies, including group sessions, may be employed as part of participant outreach. Site staff may work with community stakeholders, including community advisory board (CAB) members and voluntary health workers, to identify and recruit a community-based sample of couples.

Each site is responsible for developing its own accrual plan that should be described in the site SOP for Participant Accrual, Eligibility Determination, and Informed Consent. Note that sites may choose to separate these topics into standalone SOPs based on their preferences. SOPs should at minimum contain the following elements related to the site accrual plan:

- Site-specific accrual targets and timelines
- Description of any community sensitization plans
- Recruitment strategies relevant for accrual of couples, including:
    - Potential recruitment locations and venues
    - Plans for education about the study

    - Description of prescreening activities (as applicable)
    - Plans for referral to screening visits (and how ineligible participants will be handled)
    - Plans for recruitment materials (as applicable)
- Methods for tracking targeted versus actual accrual, and implementation of back-up plans as needed
- Methods for maintaining participant confidentiality during the accrual process
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures (if not specified elsewhere)

Study staff are responsible for updating this SOP as needed to meet site-specific accrual goals.

3.2 Site-Specific Accrual Targets and Timelines

Approximately 400 couples are targeted to be enrolled in MTN-045. Per protocol, the total accrual time allotted for this study is 12-15 months for recruitment and enrollment at each site, however sites should make efforts to accelerate this timeline as needed and in consultation with the Management Team. A subset of up to 80 participants (i.e., one or both partners from up to 40 couples) will be selected to complete a single post-survey explanatory in-depth interview (IDI) to provide further insight into the participants' survey responses and any unexpected and/or interesting examples of experiences and behaviors relevant to the study endpoints. Achievement of site-level accrual goals will be based on the number of participants enrolled in the study, not the number of Participant IDs (PTIDs) assigned.

The site-specific enrollment targets are summarized in Table 3-01.

Table 3-01: Approximate Enrollment Targets per Site

Site	Target Enrollment	Target Number of IDIs	IDI Type/Number
MU-JHU CRS	200 couples	20 couples total, up to 40 participants	At each site: 2-3 couples will be selected from the following categories: 1. Male partner opinion dominated, newer relationship 2. Male partner opinion dominated, more established relationship 3. Female partner opinion dominated, newer relationship 4. Female partner opinion dominated, more established relationship 5. Equal contributions, newer relationship 6. Equal contributions, more established relationship 2-8 couples will be selected who represent interesting cases
Zengeza CRS	200 couples	20 couples total, up to 40 participants	

3.3 Prescreening/Recruitment Activities

Prescreening for this study primarily refers to recruitment procedures undertaken by site staff in the field, prior to scheduling potential participants for their MTN-045 screening and enrollment visit. Site teams should provide education about the MTN-045 study to potential participants as outlined in their site-specific SOPs. Potential participants may be asked about their interest in contraception and/or HIV prevention, or other study eligibility criteria, during pre-screening activities to ascertain presumptive eligibility to enroll in MTN-045. Study sites will take steps during pre-screening and screening activities to minimize the potential for partner coercion or for placing participants at increased risk of intimate partner violence (IPV). Prescreening checklists to evaluate presumptive eligibility may be implemented with appropriate approvals

from site IRBs. Should sites choose to develop these materials, their usage should be outlined in site-specific SOPs. After providing study education, potentially interested participants should be scheduled for an MTN-045 screening and enrollment visit for formal evaluation of study eligibility.

Recruitment activities should be tracked on site-specific logs to monitor progress towards accrual goals. These logs should include only summary level, non-identifiable information such as: recruitment venue, total number of potential participants contacted, number of potential participants booked for screening and enrollment visits, and date of scheduled visit.

3.4 Visit Location

It is important that study visits be conducted in a private location to maintain the confidentiality and safety of the participant(s). It is also important that locations for conduct of the IDIs be quiet enough for audio-recording. Typically, visits will be conducted at the study site. Per protocol, visits may also be conducted at an alternate location (such as the participant's home for an IDI), if agreed upon by the participant and if privacy can be maintained. In the event a visit is conducted anywhere other than the study site, staff should document participant agreement to the visit location in their participant binder.

3.5 Screening and Enrollment Visit Procedures

Sites should consider visit length and make efforts to minimize participant fatigue when scheduling participants for study visit procedures.

For each study visit, completion of the following procedures for each participant is required and should be documented on the applicable Study Visit Checklist (see Appendix 1 for the study flow diagram):

1. **Obtain written informed consent for screening and enrollment**: Written IC must be obtained from each member of the couple prior to conducting any protocol-specified study procedures. Details are outlined in SSP Manual Section 4 (Informed Consent).

2. **Assign a PTID Number**: See Section 3.6 below for details.

3. **Collect locator information**: Although "provision of adequate locator information" is not a required inclusion criterion for MTN-045, sufficient participant locator information should be collected to allow for participant contact in the case of visit rescheduling and/or visit reminders for completion of the IDI (if scheduled on a different day), necessary follow-up on safety issues/social harms (expected to be rare), and/or dissemination of study results. Each site may determine the appropriate type of locator information to collect for these purposes, and suitable approaches for capturing this information.

4. **Confirm eligibility**: Eligibility of each member of the couple must be confirmed by designated staff, after written IC is obtained, and prior to completion of any data collection procedures (survey questionnaires, Case Report Forms [CRFs], or IDI). All eligibility procedures, inclusive of eligibility determination and final confirmation, should occur on the same day and not across multiples days/visits. Both members of the couple must be eligible to be enrolled. Details are outlined in Section 3.7 below.

5. **Provide introduction to DPP products via standardized materials**: Placebo versions of four product forms and a study video will be provided to sites in local languages to facilitate introduction to dual purpose prevention (DPP) products. The video and placebo products should be shown to each member of the couple before any questionnaires are administered.

6. **Administer individual questionnaires**: All questionnaires should be administered to study participants in a location that ensures participant confidentiality. Survey questionnaires will be administered to each member of the couple separately. This will include a DCE and a questionnaire with demographic and behavioral questions, both of which will be administered using a tablet computer.

7. **Administer Couple's DCE and Ideal Product Activity**: The individual questionnaires will be followed by a joint couple decision task completed by the couple together. As the couple completes the joint DCE and the ideal product activity, the interviewer will complete the Couples Observation CRF. Procedures for survey administration are further described in Section 6 (Data Collection and Management) of this SSP Manual.

8. **Complete other study CRFs as needed**: The Protocol Deviation CRF and Social Harms CRF are completed on an as-needed basis only.

9. **Provide reimbursement**: Sites must establish, in consultation with their IRBs/ECs, appropriate reimbursement for participant time/travel to conduct MTN-045 study visit(s). Reimbursement amounts should be specified in site-specific Informed Consent Forms.

10. **Schedule next visit (if applicable)**: Ideally couples enrolled into MTN-045 will complete their screening and enrollment procedures, individual survey questionnaires, and joint couple decision task on the same day. However, if that is not possible, visit procedures may be conducted over more than one day. Should this be necessary, the next visit should be scheduled. Separate visits may need to be scheduled for a subset of participants selected for an IDI (see below).

11. **Complete In-depth Interview (subset):** A subset of participants will be selected to complete an in-depth interview. Participants selected for an IDI may complete this procedure on the same day as screening and enrollment or at a separate visit scheduled **within 28 days** of their screening and enrollment visit. If the IDI is scheduled to occur on a different day, sites must also update locator information on the day of the IDI and provide reimbursement for time/travel to the clinic for the IDI. Site staff should consider the availability of all necessary interview staff (e.g., qualitative interviewers) when scheduling participants for their IDIs. Details regarding conduct of the IDIs is described in section 3.10 below.

3.5.1 Visit Checklists

Visit checklists will be used to document completion of all required study procedures and data collection forms for each visit and each type of participant in MTN-045. There are three types of visit checklists for MTN-045 (templates are available on the MTN-045 website):

1. Joint Visit Checklist (to be completed for all couples)
2. Individual Visit Checklist (to be completed individually for each member of the couple)
3. IDI Visit Checklist (to be completed for participants selected for an IDI)

Visit checklists should include, at minimum, the visit date, male and female PTIDs, a list of all required study procedures and a place for staff to indicate that each item has been completed and to write their initials and the date. Template visit checklists should be modified as needed to ensure they fit with systems at the site, then reviewed by RTI International for approval prior to implementation.

3.5.2 Preparing for the Study Visit

Site staff should do the following to prepare for MTN-045 study visits:

- Consult the Version Control Table for MTN-045 and ensure the correct versions (English and local language) of the following study materials and all necessary study equipment will be available, including:
    - MTN-045 Informed Consent Form

- Informed Consent Comprehension Checklist and Coversheet
- MTN-045 Screening and Enrollment Log
- Visit Checklist(s)
- Eligibility Checklists (male and female) and Eligibility Confirmation Form
- Study educational video (including equipment for showing the video) and placebo products
- MTN-045 CRFs
- Tablet computers to administer electronic CRFs (DCE and BDQ)

- As applicable, ensure couple has been reminded of their visit per site MTN-045 SOPs
- For IDIs (subset), also confirm:
  - IDI guide and associated IDI equipment (charged audio recorder, note taking materials, etc.) are available
  - Confirm the availability of the interview venue/room.

3.6 Assignment of Participant ID Numbers (PTIDs)

Sites should assign one PTID to each potential participant after informed consent for the study has been obtained. PTIDs are assigned in sequential order (within the applicable range) as potential participants complete informed consent. Staff should ensure that each PTID is assigned only once and should track this by using the MTN-045 Participant Link Log. To reduce the chance of error in writing/typing PTIDs throughout the visit, site teams should consider pre-populating the PTIDs on the Participant Link Log and pre-printing sticky labels that correspond to each couple's PTID assignments (Female ID, Male ID, Couple ID). When the PTIDs are assigned, a staff member would place the pre-printed sticky labels corresponding to assigned PTID on the appropriate visit checklist (Individual, Joint, IDI, respectively) at a minimum, and other paper forms if desired.

MTN-045 PTID boxes are located near the top of each CRF page. The PTIDs used for this study are five digits long and are formatted as "X-XXX-X". Note that male and female participant IDs of a couple are formatted such that the IDs are identical with a check digit that distinguishes the male and female member of the couple.

Table 3-02: PTID Breakdown

1st Digit	2nd - 4th Digit	Last Digit
Site #	Sequential for couple identification	Male vs. Female Partner
MU-JHU = 2 Zengeza = 4	100-999	Female = 3 Male = 5

3.7 Eligibility Determination and SOP

It is the responsibility of the site Investigator of Record (IoR) and other designated staff to ensure that only couples who meet the study eligibility criteria be enrolled in the study. Each study site must describe how study staff will fulfill this responsibility within their SOP(s) for Accrual, Eligibility Determination, and Informed Consent. This SOP should contain at minimum the following elements related to eligibility determination:

- Eligibility determination procedures, including:
  - Eligibility assessment procedures, including how potential for coercion from either member of the couple for their partner to join will be minimized and how risk of IPV will be minimized and managed
  - Final confirmation and sign-off procedures prior to enrollment
  - Documentation of all eligibility criteria (met or not met)
- Ethical and human subject considerations
- Staff responsibilities for all of the above (direct and supervisory)

- QC/QA procedures (if not specified elsewhere)

Should study staff identify that an ineligible participant has inadvertently been enrolled in the study, the IoR or designee should contact the MTN-045 Management Team (mtn045mgmt@mtnstopshiv.org) immediately.

Formal eligibility determination for MTN-045 should occur only after each member of the couple has signed the informed consent form (see SSP Manual Section 4: Informed Consent).

3.7.1 Study Inclusion and Exclusion Criteria

Inclusion Criteria

Each member of the couple must meet all of the following criteria to be eligible for inclusion in the study, and both members of the couple must be willing and eligible for the couple to enroll:

1. Able and willing to provide written informed consent in one of the study languages.

2. Able and willing to complete the required study procedures.

3. Currently in a heterosexual relationship (living together or not) for at least 3 months (by self-report) with the other member of the couple.

4. At time of Enrollment, expressed interest in contraception and/or HIV prevention (by self-report).

For female partner:

5. Between the ages of 18 to 40 years (inclusive) at Enrollment, verified per site standard operating procedures (SOPs).

6. HIV negative (by self-report).*

* Females should report their HIV status to the best of their knowledge and site staff should use their discretion in assessing potential participants' self-reported HIV status. Site SOPs should describe processes for evaluating HIV status reports, including how to manage cases of "unknown" HIV status.

For male partner:

7. Aged 18 years or older at Enrollment, verified per site SOPs.

Exclusion Criteria

Potential participants who meet the following criteria will be excluded from the study along with their partner:

1. Has any significant medical condition or other condition that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe (including risk for IPV as a result of study participation), complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

3.7.2 Eligibility Checklists (Male and Female) and Eligibility Confirmation Form

The **MTN-045 Eligibility Checklists** should be used to evaluate inclusion and exclusion criteria that rely on participant self-report (questions in ***italic*** font) and serve to document that all eligibility criteria have been met. An individual Eligibility Checklist is available for each member of the couple (male and female). The eligibility checklists should be administered to each member of the couple privately, to allow them an opportunity to freely express if they do not want to join the study. Per the form instructions, questions in ***italic*** *font* should be translated into local languages and administered verbatim to participants in their preferred language. The checklists must also be administered in full, even if a participant is found ineligible prior to the form's completion. This is to allow for the potential use of the "dummy" questions as justification for a couple's exclusion from the study (see Section 3.7.4 below for more details). If required by local IRBs/ECs, eligibility checklists should be approved before use.

After the eligibility checklists have been completed for both members of the couple, designated staff must document the couple's final eligibility determination using the **MTN-045 Eligibility Confirmation Form**. The IoR/designee should check the appropriate boxes on the form indicating whether each member of the couple individually met all eligibility criteria and whether the couple as a whole is eligible or not for study participation. A signature, date and timestamp must also be recorded, regardless of eligibility status. For those eligible to enroll, the act of completing and signing this form is the act of enrolling the couple into MTN-045. Staff who sign off on participant eligibility must be delegated this responsibility on the MTN-045 delegation of duties (DoD) log. All eligibility forms and checklists are available on the MTN-045 website under *Study Implementation Materials*.

3.7.3 Evaluation of IPV Risk

Per protocol, the IoR should exclude any couples from enrollment in MTN-045 if, at their discretion, either member of the couple "*[h]as any significant medical condition or other condition that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe (including risk for IPV as a result of study participation), complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives."*

To facilitate evaluation of the potential risk of IPV as a result of study participation, the following two questions have been included on both the male and female Eligibility Checklists:

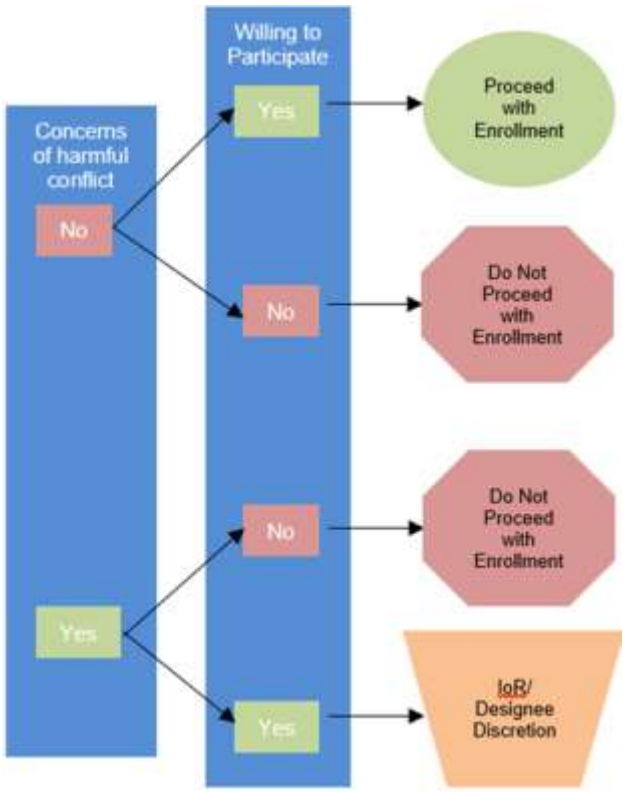
Table 3-03: Eligibility Checklist Questions to Evaluate Risk of IPV

Based on what we said about the study, do you have any concerns that your participation could create or increase harmful conflict between you and your partner?	Yes ¨	No ¨
Are you still willing to participate in the study with your partner as a couple?	Yes ¨	No ¨

Staff should administer both of these questions and then assess appropriate next steps before completing the final item on the eligibility checklist that documents if a participant should be excluded from the study per IoR discretion. See Figure 1-1 for actions based on participants' answers to these two questions, and written descriptions of actions based on answers below:

- If a participant answers "NO" to concerns of harmful conflict and "YES" they are willing to participate → OKAY to proceed with enrollment, assuming all other eligibility criteria are met
- If a participant answers "NO" to concerns of harmful conflict and "NO" they are (not) willing to participate → DO NOT PROCEED WITH ENROLLMENT → counsel and refer participant as needed
- If a participant answers "YES" to concerns of harmful conflict and "NO" they are (not) willing to participate → DO NOT PROCEED WITH ENROLLMENT → counsel and refer participant as needed to manage any IPV risk
- If a participant answers "YES" to concerns of harmful conflict and YES" they are willing to participate → PROCEED WITH CAUTION → Appropriately trained staff should have a conversation with participant to elicit specific concerns about what harmful conflict they foresee the study could cause and their rationale for still being willing to enroll. Based on this conversation, the IoR/designee should determine whether enrollment would be unsafe for the participant. Ultimately, the IoR/designee can determine whether the participant is ineligible due to risk of harm, even if they still express willingness to participate. Counseling and referrals should be provided as needed to manage any IPV risk.

Figure 1-1: Harmful Conflict Decision Diagram



All conversations, counseling and referrals related to potential conflict and IPV should be fully documented in visit notes or other source documents. See also SSP Manual Section 5 (Safety and Counseling Considerations) regarding participant safety and IPV referrals.

3.7.4 Dummy Questions on Eligibility Checklists

Due to the small number of inclusion and exclusion criteria for MTN-045, and to minimize the potential risk of social harms and/or IPV, several dummy questions exist on the eligibility checklists, indicated by Yes/No response options with a hashed background. The dummy questions should also be read verbatim to participants but are ultimately not used in determining a participant's eligibility. Should a participant express concern that participating in the study with their partner may cause harmful conflict in their relationship, staff may, at their discretion, rely on responses to the dummy questions to justify the participant's non-enrollment in the study. Using this approach will help minimize social harms and/or IPV by providing a "benign" reason to the participant's partner why the couple is ineligible for study participation. Alternatively, no specific reason needs to be provided to the couple regarding their ineligibility. Staff should use their discretion and discuss the preferred approach with the member of the couple who expresses that enrolling in the study could create harmful conflict and, because of this, are unwilling to enroll. The dummy questions on the male and female behavioral questionnaire are shown in Table 3-04:

Table 3-04: Dummy Questions on Female and Male Behavioral Eligibility Checklist

Do you and your partner have children together?	Yes ¨	No ¨
Are you currently employed?	Yes ¨	No ¨
Are you and your partner married to each other?	Yes ¨	No ¨

3.8 Screening and Enrollment Logs

The DAIDS policy on Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials requires that study sites document screening and enrollment activity on Screening and Enrollment Logs. These provide a comprehensive picture of all participants screened and enrolled in the study. This log must be maintained in hard copy. When recording the reason(s) for screen failure/discontinuation, staff should use the codes listed at the bottom of the sample log. In addition to the Screening and Enrollment Log, each participant that is screened for MTN-045 should have a completed Participant Status Form (PSF) CRF, which will indicate enrollment into MTN-045 or reasons for non-enrollment. Each couple that provides informed consent is provided with the next sequential PTID, with a designated "check" digit on the end which will be assigned based on sex (this structure indicates that the male and female participant are undergoing screening and enrollment as a couple). Couples in which the male and female partner both meet all eligibility criteria and whose final sign-off of enrollment status is documented on the **MTN-045 Eligibility Confirmation Form** are considered enrolled in the study.

There is no cap to the number of screening attempts allowed by potential participants; this is to be decided by the site IoR, using their discretion. If a potential participant rescreens for MTN-045, a new line should be used on the Screening and Enrollment Log documenting the new attempt, and the same PTID previously assigned to the participant should be used.

An example of a Screening and Enrollment Log can be found on the MTN-045 website. Sites are encouraged to modify this template as needed. This log must include, at minimum, the MTN-045 Male and Female PTIDs, screening date, screening attempt, enrollment date or reason for non-enrollment (if applicable), and staff initials and date.

3.9 Weekly MTN-045 Progress Reports

Once MTN-045 accrual is initiated, study staff will report the total number of couples screened and enrolled to RTI on a weekly basis, along with other key progress indicators, as necessary. RTI will send a Screening and Enrollment report to the MTN-045 Management Team prior to each scheduled management team call.

3.10 In-Depth Interview

3.10.1 IDI Selection

Summary of MTN-045/CUPID IDI Selection considerations
Per language in the protocol that describes the purpose of the IDIs, the impetus for the qualitative component of MTN-045 is to "provide further insight on the participants' survey responses and on any unexpected and/or interesting examples of experiences and behaviors relevant to the study endpoints." Additionally, the protocol specifies that, "Whenever possible, we will also compare study sites and explore differences or similarities related to product preferences due to different socioeconomic, cultural and geographical contexts." With that in mind, the IDI selection criteria for MTN-045 take into consideration the following elements:

1. Preference
    a. Notable differences or similarities between individuals' preference and the couple's preference
    b. Preferences around product attributes (particularly with respect to any differences that may be related to sociodemographic factors)
2. Relationship dynamics: interpersonal factors and influence on decision-making
3. Site differences: any salient differences between preference at a site level

Selection Plan
The following plan is intended to respond to the three above-listed priorities for the IDI component of MTN-045. RTI will monitor incoming data (through Qualtrics, REDCap, and

debriefing reports) to identify potential needs to re-adjust this plan during the course of data collection.

1. To address the goal of gaining a better understanding of factors that impact preference, couples will be selected based on the response to Question #4 on the CO CRF, which asks "Which partner's opinion contributed to the final product selections?" Couples will be selected to participate in IDIs from each of the three response options.
    a. Male partner's opinion dominated
    b. Female partner's opinion dominated
    c. Equal contributions
2. To meet the goal of addressing how relationship dynamics within a couple may influence decision-making, 12-18 out of the 20 couples at each site should be selected based on the length of their relationship. Although length of relationship is only a small piece within the larger picture of the interpersonal factors of a relationship, it is related to many other factors of interest (age of members of the couple, cohabitation, having children together). This will be based on the response to Question #10 on the female partner's BDQ CRF ("For how many years have you and your partner been in a sexual relationship? If you have been in a relationship for less than one year, how many months have you been together?"), and stratified into two categories, though site staff selecting couples should look for a range of relationship lengths within each of these categories:
    a. Newer relationships: Responses to BDQ Question #10 that are marked as ≤3 years old
    b. More established relationships: Responses to BDQ Question #10 that are marked as >3 years old
3. To address the goal of exploring any site level differences, the 40 couples to be recruited in this study will be split evenly between the two sites.

Site discretion

For the 20 couples to be recruited at each site, the MTN-045 Management Team accords the site teams significant autonomy in selecting couples or members of couples who can provide rich information to help further understand the three above-stated elements. This means that site teams should particularly look for individual participants or couples who:

1. Are able to articulate their rationale for preferences and decision-making
2. Are willing to complete an IDI the same day or will be willing to return to site within 28 days to do so
3. Fit within the selection plan:
    a. Per selection criteria: As described above and outlined in Table 3-01, participants who fall into each of the three response options for Question #4 on the CO CRF *and* who represent a range of relationship durations, based on Question #10 on the BDQ CRF OR
    b. Interesting cases: Represent a particularly interesting or impactful experience, (regardless of how they fall into the stratifications for relationship duration and dominance of opinion in Joint DCE).

Table 3-05: Selection Criteria and Target Numbers for MTN-045 IDI Selection

	Male partner's opinion dominated	Female partner's opinion dominated	Equal contributions
Newer Relationship	2-3	2-3	2-3
More established relationship	2-3	2-3	2-3
Subtotal			12-18
Interesting case			2-8
Total			20

3.10.2 Procedures for Selected Participants

For the subset of selected participants, the IDI will take place once the appropriate study visit procedures have been completed.

To begin the IDI, delegated staff should greet the participant, introduce themselves and explain their role in the discussion (e.g., interviewer/facilitator) and help the participant(s) get settled and comfortable in the interview space. The interviewer will describe how the interview will work, including that it will be recorded. The interviewer may start the discussion with an ice-breaker to increase rapport.

Split Visits: If IDI participants are not able to complete the interview on the same day as other study procedures, they may be rescheduled to come back and complete the interview on another day, ideally within one week of the initial visit, though it may be up to 28 days later. Any split visits must be documented in participant file notes.

3.10.3 After the IDI is Completed

There are a number of steps to follow after the IDI is complete. They are as follows:

1. Immediately following the IDI, the participant(s) will be thanked and reimbursed according to site-specific IRB-approved informed consent forms.
2. The interviewer will complete their notes and complete the PSFs.
3. A debriefing report (DR) will be completed on the same day as the interview or within 24 hours if it is not possible to complete it on the same day. Once completed, the DR must undergo a QC process at the site prior to being circulated to the study team.

Further details on the management of the audio-files, transcription/ translation process, discussion notes, debriefing reports, CRFs, and transcripts is described in SSP Section 6 (Data Management).

Appendix 1: Study Visit Flow Diagram