Section 5. Study Visit Procedures

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This section provides information on requirements for study procedures in MTN-032, including screening, enrollment and participant follow-up visits.

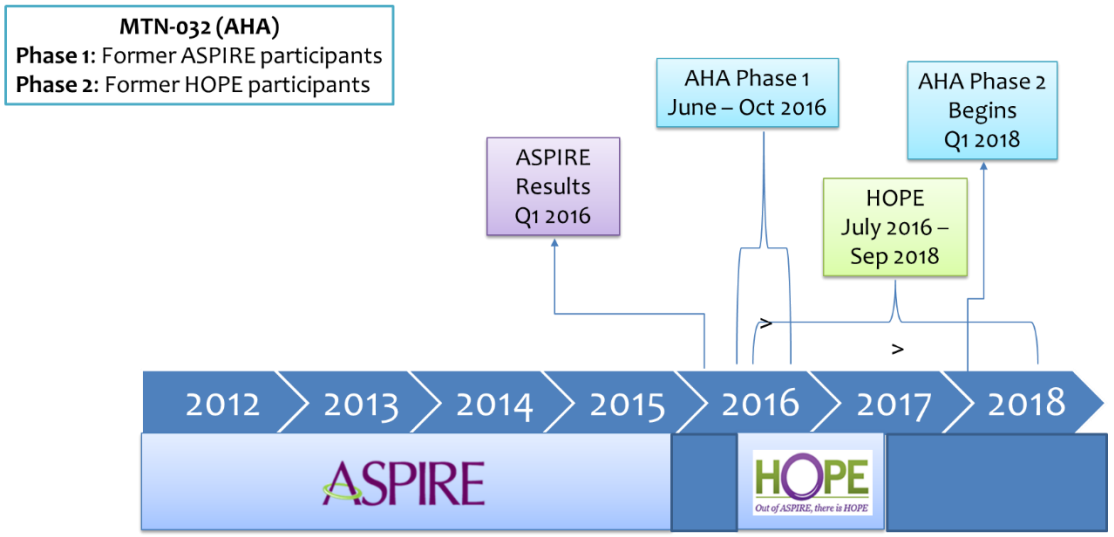
5.1 Visit Location

All visit procedures are expected to be completed in a location agreed upon by the participant(s).

5.2 Study Visit Timing

Overview. For each phase of MTN-032, it is recommended that all procedures be completed on one day, however, participants may complete up to two visits, depending on whether the screening and consent procedures occur on the same day as the qualitative interview (IDI or FGD). For phase 2, AHA activities will begin as participants begin exiting from HOPE, as per the study timeline overview below (Image 5-01).

Image 5-01: Study timeline overview



Target Days and Visit Windows: There are no specific target dates or visit windows for MTN-032. Rather, there are guidelines for when qualitative data should be collected, as described here.

AHA Phase 2 visits for female participants should occur as soon as possible after she exits from HOPE and after the participants' last expected ring data from HOPE is available. If there is an unexpected delay in receiving results for any potential participant, sites should email the MTN-032 Management Team who will work with the site to determine next steps.

AHA Phase 2 visits for male participants should occur after their female partner has exited from HOPE. Sites should choose two FGD dates for male participants, one after all HOPE participants from the 1st 50% recruitment list have exited from HOPE and one after all HOPE participants from the 2nd 50% recruitment list have exited from HOPE. Male partner IDI visits should be scheduled only if special cases arise, or if participants are unwilling or unable to attend the FGDs. Prior to conducting male partner IDIs, sites should consult with the 032 Management Team to discuss the rationale for conducting the IDI.

For more information on screening and accrual procedures, see SSP Section 3.

Split Visits: If an IDI participant is not able to complete the interview in one day, s/he may be rescheduled to come back and complete the rest of the interview on another day, ideally within one week of the initial visit. Any split visits must be documented in participant file notes. If an individual is unable to complete participation in an FGD (i.e. s/he leaves the FGD before it is complete), this should be documented in the debrief notes for the FGD as well as in the participant file notes. S/he will not rejoin another FGD unless determined necessary by the Management Team.
Missed Visits: If an enrolled IDI participant does not present for a scheduled IDI, study staff should document this in the participant file notes and reschedule this visit as soon as possible. Every effort should be made to reschedule the IDI for a convenient time for the participant. If a participant is re-scheduled on three separate occasions and continues to miss her visit, study staff should consult the MTN-032 Management Team to determine if the participant should continue to be considered for recruitment/enrollment. If an FGD participant does not present for a scheduled FGD, study staff should consult the MTN-032 Management Team to determine if she/he should be rescheduled to participate in a remaining FGD or an IDI.

5.3 Visit Codes

In MTN-032, there will not be visit codes. Rather, the visit date and PTID will be recorded on all documentation.

5.4 Visit Scheduling

Ideally participants enrolled into Phase 1 or 2 of MTN-032 will have their IDI/FGD conducted on the same day as enrollment, with the exception of conducting informed consent procedures 1-2 days in advance of focus group discussions or IDIs when necessary. However, there may be some individuals who require the IDI/FGD to be scheduled for a more convenient time, and this should be documented in the comments section of the Participant Status Form (PSF). Additionally, staff may need to be flexible in scheduling IDIs/FGDs by allowing for after-hours and weekend meeting times, and/or alternate venues to make the meetings convenient for the participants, provided the venue is conducive for the IDI/FGD (see Visit Location above). Staff need to consider the availability of all necessary interview staff when scheduling participants for their IDI/FGD.

As noted in Section 3 of this manual, any change in interview modality assignment must first be approved by the MTN-032 Management Team, and documented on the Recruitment List and the Screening and Enrollment Log.

5.5 Preparing for the IDI/ FGD

Before each data collection visit, the following should occur:

- Ensure the participant meets eligibility criteria, as outlined in Section 3 of this manual.

- Ensure the correct versions (English and local language) of the discussion guide, tools, CRFs and informed consent are printed and ready for use, consulting the version control document on the MTN website as needed (http://www.mtnstopshiv.org/node/7104).

- For Phase 2: Ensure that all expected drug results for the participant have been received and the drug feedback over-time tool has been updated with the add-on as needed, as per section 5.6.2.
- Ensure the correct data collection tools listed below are prepared, and review them prior to the interview.
    - Phase 1: PK and residual ring results
    - Phase 2 female IDI participants: drug feedback over time tool (including supplemental add-on), opinion tool, stickers, & as needed, props (demonstration ring, vulva puppets, and penis models)
    - Phase 2 male participants: opinion tool, stickers, & props (demonstration ring, vulva puppets, penis models, and pelvic models to explain dapivirine ring placement if needed)
    - Phase 2 female FGDs: MTN-032 management team will provide further guidance on tools for these FGDs should they be required
- For male partner activities: if site staff believe male partner participants 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.
    - Note for second probe under question 5 on male partner FGD and IDI guides: if information on the HOPE study was provided to male participants by staff as part of MTN-032 Phase 2, interviewers should ensure they probe on what male partners knew about the HOPE study *prior* to their involvement with MTN-032.
- For Phase 1 only: Ensure staff is aware of which category of participant they will be interviewing (i.e. age group, adherence level) and HIV status (for IDI only).
- Ensure the applicable staff member has reminded the participant of her or his visit, per site SOP.
- Confirm the availability of the interview venue.
- Confirm that the audio-recorder is charged and/or has batteries and is functioning correctly.

5.6 Data Collection Procedures

The IDIs/FGDs will be conducted in a private location to maintain the confidentiality and safety of the participants. This may be the ASPIRE/HOPE clinic, a community hall, the participant's home (for IDIs), or another venue preferred by the participant that is quiet enough for audio-recording (see section 5.1 above). The visit checklists provided to MTN-032 sites should guide the order of procedures for each IDI/FGD. See Section 5.6 for more information on visit checklists.

Upon arrival for the IDI/FGD visit, the participant will be greeted and offered refreshments (if feasible). The MTN-032 staff will introduce themselves and explain their background, roles during the discussion (e.g. interviewer/facilitator, observer, note-taker). The MTN-032 staff will then conduct the written informed consent procedures. Following the informed consent process and prior to the interview, a staff member will assign a PTID. Some eligibility criteria will be confirmed prior to contacting the participant whereas other eligibility criteria may be confirmed during and after conducting the informed consent; see Section 3 for further details on eligibility determination and Section 4 on conducting the informed consent process.

The PSF form should be initiated prior to the discussion and completed after the discussion is finished. The demographic (DEM) and Behavioral Assessment forms may be administered either

before or after the IDI/FGD. However, the presentation of drug feedback to female participants must be administered during the IDI or, if applicable, before any FGD activities (to ensure that it can be done with each participant individually). The DEM and BA forms and any presentation of individual drug feedback results must be administered to participants one-on-one in a private location. Male participants should not be shown their female partners' drug feedback information.

The IDI/FGD will follow a discussion guide but will allow for iteration, probing and digression on relevant themes. IDIs/FGDs will be audio-recorded and later transcribed and translated by study staff. Following the IDI/FGD, the participant(s) will be thanked for their time and reimbursed for travel and time. For qualitative interviewing techniques, see Appendix 5-1.

Immediately following each IDI/FGD, the facilitator should complete their notes, ensure that any markings made on relevant tools (e.g. drug feedback over time tool) are fully explained through comments on the tools, and update and/or complete the PSF. A debrief report should be completed on the same day as the discussion and undergo a QC process prior to being circulated to the study team.

Further description of the management of the audio-files, transcription/ translation process, discussion notes, debrief reports, CRFs, visit checklists and transcripts is described in Section 7 Data Management.

Note: All interviewer-administered CRFs and guides should be administered in the primary language of the participant (as indicated on the ICF). Any deviation from this should be documented in the participant file notes.

Note: Sites should monitor the length of interviews, other study procedures and study visits overall to identify and address inefficiencies in a timely manner. Sites are to notify and work with the management team if any visit or procedure takes longer than expected.

5.6.1 Phase 1 Presentation of tools:

For Phase 1, individualized tools depicting drug level results will be generated for each female participant and shipped to sites prior to accrual. Staff members should review the individualized tool for each participant in advance of the scheduled IDI or FGD. A sample tool is available on the MTN-032 website, and a legend/ instructions are provided in Section Appendix 5-2.

The presentation of the drug feedback results, must be administered before the FGD (so that it can be done with each participant individually) or during the IDI. Staff should stay neutral during the presentation of the results. Staff must remember that the purpose of the tool is to stimulate discussion and NOT to place blame on the participant for any low drug detection or for any discrepant information. During the presentation of the results, staff members should ensure participant's understanding of the illustration as well as of her results; furthermore staff members should be cognizant of the participant's reaction upon hearing the results and should record this immediately either directly on the PSF or on separate notes that can later be transcribed on the PSF keeping in mind the categorical responses.

Note that for FGD participants, written informed consent may have already occurred prior to the date of the scheduled FGD. In this case, staff should ensure that all required documentation is in place for all participants prior to the start of the FGD.

5.6.2 Phase 2 Presentation of Tools:

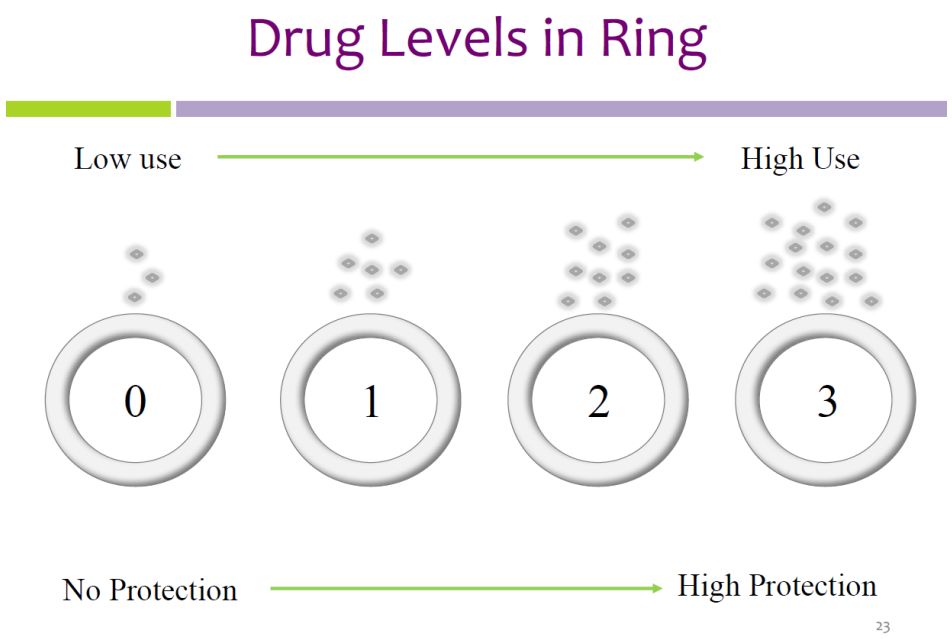
Provision of Adherence Data for female participants

The drug feedback over-time tool used in HOPE will be used to discuss drug (RD) feedback with participants. Prior to the scheduled visit, sites will make a certified copy of the participant's over-time tool from HOPE, and using a supplemental add-on to the tool, fill-in any remaining drug feedback data onto each individual's over-time tool. Sites should work with HOPE study teams to

download the remaining drug data via Atlas. The supplemental add-on to the tool is available in Section Appendix 5-3 and posted on the MTN-032 website. The supplement sheet should then be taped or stapled to a certified copy of the participant's HOPE over-time tool so the participant has a complete timeline of her use from HOPE enrollment to Month 12. If a participant has already come to receive her final 3 months of RD feedback from the HOPE study team, it is acceptable to make a certified copy of the HOPE RD Feedback Over Time Supplement used in this session for the MTN-032 file. For participants who did not accept a ring after the 8th month of participation in HOPE, the supplement should still be added and the notes should describe why there is no data for a particular month. Staff members should review the over-time tool for each participant in advance of the scheduled IDI.

While participants will have received their drug data up to their 8th month of participation from the HOPE counselors, interviewers need to familiarize themselves with the numbering system that corresponds to level of protection provided by the ring to understand what is being presented. As seen in image 5-01 below, the numbers represent a scale from low to high use that corresponds to no to high protection from HIV, where a level of 0 means low use of the ring and no protection from HIV, and a level 3 means high use and high protection.

Image 5-01: Depiction of drug levels visual used in HOPE counseling



The drug level results will be presented during the IDI for female participants. The interviewer should show the participant her over time tool (from enrollment through month 12) when the interview guide indicates. The results should not be presented in a way that it is confrontational or judgmental. The interviewer should give the participant some time to review her over-time tool and process the additional months she is just now receiving before continuing with the questions on the interview guide.

REMEMBER: Staff are not there to provide counseling, re-assurance or an explanation of her results. The purpose of presenting this information to the participant is to discuss her reaction and thoughts about her results as indicated on the guide. If she has questions about her results that cannot be answered by the interviewer, the interviewer should let her know that she can be referred to another staff member after the interview.

Use of Opinion Tool and Emoji Stickers

For all interview modes (female IDI, male partner FGD and IDI), the opinion tools (one for male partners and one for female participants) should be used when mentioned on the interview guides. Each participant should be given a set of two emoji sticker sheets and an opinion tool. The interviewer should then use the guide and probing techniques to go through the boxes one by one, starting with the left column and moving right, asking participants to choose the stickers that best represent their response to the items in each box, then exploring why the participant chose the stickers.

Use of Props: Demonstration Rings, Penis Models, and Vulva Puppets during Male Partner FGDs/IDIs and optionally during female IDIs

When prompted on the interview guide during questions about influence of ring on sexual experience, interviewers should present demonstration rings, the vulva puppets and penis models to the group or individual, asking for participants to use the props to demonstrate how the ring affected their sexual life (if at all). Interviewers/Facilitators will need to ensure that participants orally describe what they are doing with the props and why, so that the information from physical demonstrations can be captured on the audio-recording.

5.7 Visit Checklists

Examples of checklists detailing the protocol-specified procedures that must be completed at the MTN-032 study visit are available on the MTN-032 website (http://www.mtnstopshiv.org/node/7104). These checklists should be modified as needed to ensure they fit with systems at the site, then reviewed by the MTN LOC (FHI 360) for approval prior to implementation. The checklist also specifies the data collection forms that must be completed at the visit.

Appendix 5-1 Qualitative Interview Techniques[1]

IDI Techniques

- **Maintain Confidentiality.** Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned during the interview. This is especially important when interviewing participants about their sexual behaviors. Ask FGD participants to be respectful of confidentiality, and not to share personal information from fellow FGD participants.

- **Remaining Neutral.** It is especially important to be on guard against asking leading questions and influencing responses. Leading questions are those that imply a value judgment on your part. This can bias the responses that you will obtain because if the participant disagrees with you, they may be reluctant to state it.
    - *Biased question: "I know that most smart people in this community always use condoms, don't they?"*
    - *Better phrasing: "I have heard some people in this community say that most smart people use a condom, and others say that they know smart people who don't use condoms. What do you think?"*

- **Probe for Depth.** As much as possible ask follow up questions and probe for a deeper understanding of what the participant is saying. Examples of probing phrases might be: "Why?" "How did you feel when that happened?" "What did you do next?" "What do you think?" "What happened then?" "Can you tell me more?" "Could you describe X? I'm not sure I understand." Such probing also may require extra patience on the part of the interviewer.
    - *Example: Can you tell me more about why you didn't feel you could ask him to use a condom?*

- **If Uncertain, Verify Responses.** When you want to be sure that you have heard clearly what the participant said or that the information is accurate. You may ask them to repeat their response, or sometimes better, you can reflect the answer back to the participant.
    - *Example of reflecting back: So you told him that you think it's a sign of being responsible if you avoid sex while drinking?*

- **Do Not Respond to Questions.** If the participants ask you questions that are the focus of the interview, do not answer them. Your answers might influence how the participant will answer the rest of the questions. Instead, turn the question around and ask them what they think. You may also offer to answer questions after the discussion is complete and/or refer them to someone else who can answer their question.
    - *Example: Well, I was hoping you could help me understand what people in this community say about how you catch the HIV virus.*

- **Be Patient.** It is not necessary to be asking questions every minute. Creating pauses and allowing silence can permit the participant to think more deeply about the topic. Don't be afraid to

[1] The Qualitative Interview Techniques section is adapted from the following reference: Mack, Natasha, Cynthia Woodsong, Kathleen MacQueen, Greg Guest and Emily Namey. Qualitative Research Methods: A Data Collector's Field Guide. RTP, NC: Family Health International, 2005.

wait quietly while they think about a response or further probe, but be reassuring in your body language so the participant knows are genuinely interested in what she/he has to say.

- **Do Not Interrupt Participant's Work.** The participant is doing a favor to answer the questions. If the participant must interrupt the interview to attend to a child, a customer, a neighbor, use this time productively to review your notes and think about what else you would like to ask.

- **Handle Time Wisely.** Always note the time when the interview begins and ends. As you begin the interview, evaluate how much time you may have with this participant and what are realistic goals for asking questions from the interview guide. Ideally, the interview will flow like a conversation rather than a series of questions and answers.

- **Be Truthful.** In obtaining informed consent or in responding to questions from participants during the interview, provide brief, truthful answers about the objectives of the study, the likely benefit to the community.

- **Monitor Body Language.** Be sensitive to your participant's body language and aware of your own. Avoid body language that may send the signal that participants are giving "correct" answers, or that you approve of, or reciprocally, that you are wasting your time.

FGD Techniques

- The primary responsibility for the flow of each focus group session rests with the facilitator. Facilitators should keep the following "do and don't" list in mind.

A good facilitator does:	A good facilitator doesn't:
Show flexibility	Dictate the course of discussion
Show sensitivity	Lose control over the conversation
Have a sense of humor	Judge comments or be an "Expert"
Link group ideas together	Inform or educate during the group
Encourage everyone to participate	Lead a Question and Answer session

Asking Questions and Probing

The goal of the facilitator during the focus group session is twofold: (1) to create a natural discussion in which the facilitator participates very little, i.e., she/he should "disappear," (2) to unobtrusively steer the discussion through all the important questions in the guide and at a pace which will allow for all topics to be adequately covered. Much of what happens in the focus group will rely on the facilitator's ability to monitor the tone and the group and make quick judgments about when, how and if to reenter the conversation as the discussion progresses.

To the extent possible, the discussion should flow in the order presented in the applicable guide. However, the facilitator should be prepared for things to be mentioned out of order, and she/he should not ask participants to stick with the established sequence if it would be disruptive. It is helpful to tick questions off on the guide as they are discussed, in the event that the discussion "gets ahead of itself." Then, when it is appropriate, the facilitator can return to the questions that were skipped.

Tips for Facilitators:

• **Be prepared**. Have everything you need to conduct the focus group with you and in order. Get all your materials together. Make sure flipcharts and additional tools needed are prepared. (See IDI, FGD and EI visit checklists).

• **Introduce yourself individually** as participants gather. Make small talk. Thank participants for coming.

• **Limit the amount of time you talk** once the session begins. Attempt to get a question on the floor and let the participants kick it around with limited direction from you.

• **Steer the conversation** mainly by asking for experiences, thoughts or definitions. Ask people not only to talk about themselves, but to talk about what others like them think, say or do.

• **Try to include as many participants as possible**. You may refer to an individual if the current conversation relates to something that individual has said earlier in the discussion. For example, *What you are describing sounds very similar to (or very different from) what Martha was talking about earlier. What do you think about this Beverly?*

• **Do not force responses by using leading questions** or by paraphrasing what participants have said. Instead, use neutral probes or repeat what the participants say in their own words.

• **Do not use evaluative comments** like "good" or "That's interesting." Do provide positive enforcement by looking interested, saying uh-huh, or asking a follow-up question. Make sure that you **provide consistent enforcement for all comments** (unless you are trying to steer conversation elsewhere). Comments such as "I see" and neutral probes such as *"Any other thoughts about this?"* and *"Who else has some ideas about this?"* are acceptable. Questions may also be addressed to the group: *"What do you [the group] think about what [name] just said?*

Tips for Note-Takers:

• **Be prepared**. Have everything you need to conduct the focus group with you and in order.

• Even if you are audio recording the group, it is important to remember that **if the recording fails your notes will be the only documentation** of what occurred during the group. Make sure you have a sufficient number of tapes handy, or sufficient memory in your digital recorder. Check the tapes and recorder before the group begins. Record the time and date and the archival number prior to beginning the group.

• It is the **note-taker's responsibility** to note observational details such as: body language, interruptions, silent agreement, indications of group mood, irony or contradictory statements when the meaning is opposite of what is said.

• It is the note-taker's responsibility to **capture well-said quotes**, word for word if possible.

Appendix 5-2: Instructions for Visual Tools for Phase 1

It is important to remain neutral when presenting these tools to female participants and discussing their experience using the ring in ASPIRE and/or HOPE. If needed, reassure the participant that the purpose of the tool and the discussion is not to accuse her or other participants of non-adherence, but instead to discuss challenges using the ring and to understand their experiences. It is also extremely important to remind participants that what they say regarding their ASPIRE and/or HOPE results will NOT have any impact on their participation in any other studies, if relevant.

Instructions for Staff on Presenting the Adherence Trajectory Tool:

The Adherence Trajectory Tool is to be used to ask female participants in IDIs and FGDs about their perception of their and other women's overall adherence pattern throughout ASPIRE. The different lines represent examples of adherence patterns, and are intended to stimulate discussion about which pattern a participant thinks is most illustrative of her behavior. Patterns include:

A) Consistently adherent,
B) Consistently non-adherent,
C) Non-adherent at the beginning and adherent by end,
D) Adherent at the beginning and non-adherent by the end, or
E) Inconsistently adherent throughout the study.

The x-axis represents overall duration of the study and not specific timepoints (i.e. when adherence pattern changes on lines C and D, this represents a change at some point in the study rather than a change at a particular point in time). The y-axis represents adherence level from low to high.

Instructions for Staff on Presenting the Individual Drug Level Results Visual Tool:

RTI will provide sites with the Individual Drug Level Results Visual Tool for each participant listed on the MTN-032 Recruitment Lists. The tool is a visual depiction of that participant's specific drug detection results from ASPIRE. This tool is meant to be used as a way to provide participants with their drug detection results from ASPIRE in a simple fashion in the hopes that it will spark discussion about that participant's experiences of using or not using the ring.

Below are descriptions for each of the four images that may appear on the individual's tool. Dots represent the detection of dapivirine. Green background means that the ring is considered to have been used, based on the level of dapivirine detected in the blood or the returned ring. Therefore:

- The image of the ring with a green background and few dots suggests the ring was used.
- The image of the ring with no background and many dots, suggests the ring was not used.
- The image of the blood vial with green background and many dots, means the amount of dapivirine detected in the blood suggests the ring was used.
- And, the image of the blood vial with no background and no dots, means the amount of the dapivirine detected in the blood suggests the ring was NOT used.

MTN-032 INDIVIDUAL DRUG LEVEL RESULTS TOOL LEGEND

GREEN BACKGROUND; FEW DOTS
Ring appears used

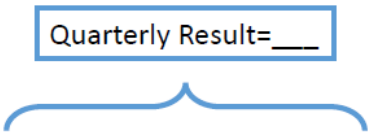
NO BACKGROUND; MANY DOTS
Ring does NOT appear used

GREEN BACKGROUND; MANY DOTS
Amount of dapivirine detected in blood suggests ring was used

NO BACKGROUND; NO DOTS
Amount of dapivirine detected in blood suggests ring was NOT used

Appendix 5-3 Residual Drug Feedback Over Time Tool Add-On for Phase 2

The full tool can be found on the MTN-032 site, http://www.mtnstopshiv.org/node/7104. Complete the last 3 months of RD feedback with available results and attach to the original RD Feedback Over Time Tool used during HOPE.



M9-M10	M10-M11	M11-M12

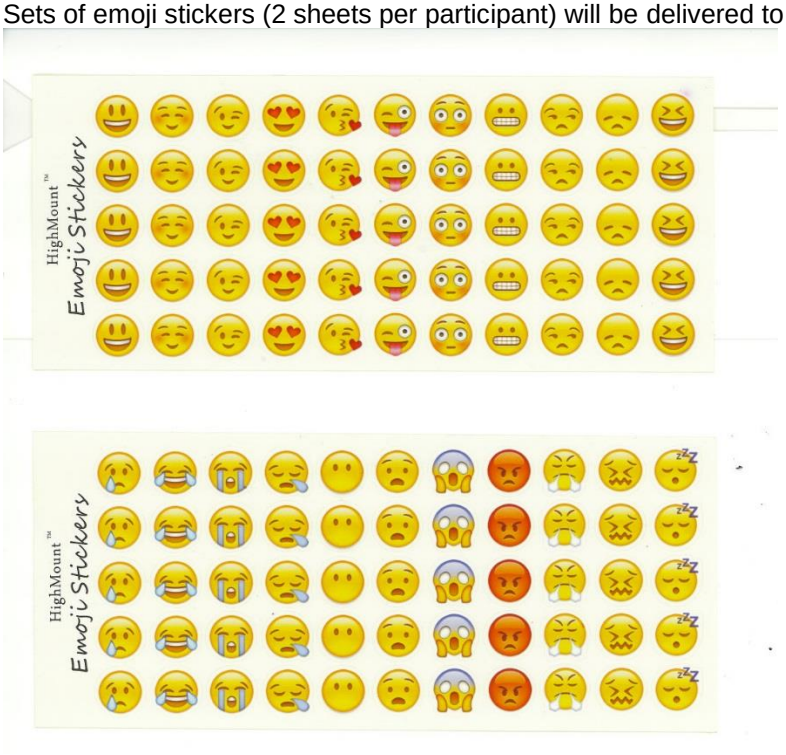
Instructions to site: complete the remaining 3 columns and quarterly result feedback prior to the IDI. Attach to the HOPE Residual Drug Feedback Over Time Tool.

Residual Drug Feedback Over Time, MTN-032 Phase 2 V1.0, 21DEC2017

MTN-032 PTID _____

Appendix 5-3 Opinion Tools and Emoji Stickers for Phase 2

Sample of Emoji Stickers:
Sets of emoji stickers (2 sheets per participant) will be delivered to sites by RTI.



Sample of Opinion Tools:
One copy of each tool (one for female and one for male) will be sent to sites in the packet with emoji stickers. Electronic copies for download can be found on the MTN-032 site, http://www.mtnstopshiv.org/node/7104.

Date: _____ PTID: _____

MTN-032 Phase 2 Opinion Tool – Female Participants

Instructions: When prompted on the interview guide, ask the participant to place an emoticon sticker(s) in each box that best represent the participant's, their partner's, and other people's opinion about the dapivirine ring, and explain why they chose the sticker(s).

YOUR OPINION		***YOUR PARTNER'S OPINION***		***OTHERS' OPINION***
*(**Your** opinion of the dapivirine ring: NOW)*		*(Your **primary partner's** opinion of the dapivirine ring: NOW)*		*(**Other participant's** opinions of the dapivirine ring)*
*(All opinions **you** have had of the dapivirine ring: OVER TIME)*		*(All opinions your **primary partner** has had of the dapivirine ring: OVER TIME)*		*(Opinions of **other people in the community** or any others)*

Date: _____ PTID(s): _____
FGD # (if applicable): _____ _____

MTN-032 Phase 2 Opinion Tool – Male Partner's

Instructions: When prompted on the focus group/interview guide, ask the participants to place an emoticon sticker(s) in each box that best represent the participant's, their partner's, and other people's opinion about the dapivirine ring, and explain why they chose the sticker(s).

YOUR OPINION		***YOUR PARTNER'S OPINION***		***OTHERS' OPINION***
*(**Your** opinion of the dapivirine ring: NOW)*		*(**Your female partner's** opinion of the dapivirine ring: NOW)*		*(**Other men's** opinion of the dapivirine ring)*
*(All opinions **you** have had of the dapivirine ring: OVER TIME)*		*(All opinions **your female partner** has had of the dapivirine ring: OVER TIME)*		*(**Any other people's** opinion of the dapivirine ring)*

Appendix 5-4 Props: Demonstration Rings, Penis Models, and Vulva Puppets for Phase 2

Sample Demonstration Ring:
Sites to use demonstration placebo rings from HOPE.

Sample of Vulva Puppet & Penis Model:
Two vulva puppets and two penis models will be delivered in person to each site.