



MTN-038 Behavioral Measures

WGHI/RTI International
San Francisco, CA

Overview of Behavioral Measures

- Behavioral CRFs – covered by SCHARP
 - Ring Insertion and Removal: ease or difficulty with ring insertion, reason for not inserting it herself
 - Ring Adherence: Number, timing, duration or removals and expulsions, with reasons
- CASI questionnaires – covered by SCHARP & RTI at later date
 - Enrollment, Visit 6 (Day 28), Visit 8 (Day 56) and Visit 9/PUEV (Day 91)
 - Administer Visit 9/PUEV survey if early PUEV or early termination

Overview of Behavioral Measures

- CASI questionnaires – topics

Topics	ENR	V6 (Day 28)	V8 (Day 56)	V9/PUEV (Day 91)
Motivation to Join	✓			
Demographics	✓			
Vaginal Practices	✓	✓	✓	✓
Sexual History & Partners	✓	✓	✓	✓
Recent Sexual Behavior	✓	✓	✓	✓
Drug/alcohol	✓			
Other HIV px methods	✓			
Adherence (frequency of removal/expulsions)		✓	✓	✓
Acceptability		✓		✓
Preference (attributes, dual indication, duration)				✓

Overview of Behavioral Measures

- By the way! New CASI uses “Illume” and will be online instead of an app on handheld tablets.
 - Here’s a peak at the new format:
 - Separate training will be provided by SCHARP and RTI to review format and content in more depth

Survey

Secure | <https://hptn.datstathost.com/Collector/Survey.ashx>

MTN 038 Questionnaire

2%

2. Please enter a number between 1 and 10.

3. What is your favorite day of the week? Please choose one option.

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday

4. What is your favorite music?

◀ Previous Next ▶

Overview of Behavioral Measures

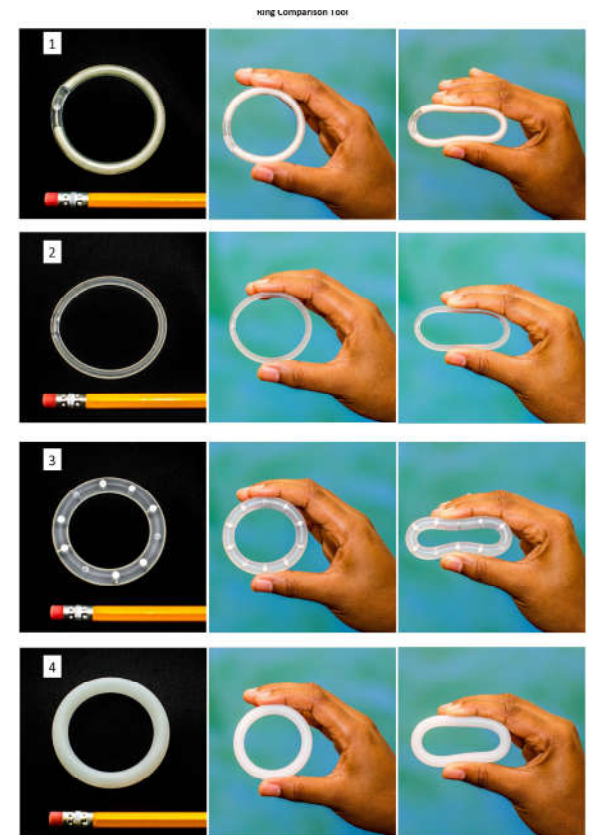
- Qualitative: In-depth Interviews
- Conducted at Visit 9/PUEV or Early Termination Visit
- Topics
 - Degree to which participants like/dislike using the IVR
 - Attitudes about ring attributes, dosing regime, willingness to use IVR in future
 - Effect on sex and partners' reactions
 - Challenges using IVR in relation to hygiene, menses, sex
 - Interest/preference in single vs. dual-purpose indications (MPTs)
 - IVR in comparison to other HIV prevention methods

In-depth Interviews (IDIs)

- Subset of participants invited to IDI
 - Ideally 8 IDI participants per site, ~24 total
 - Eligibility: penile-vaginal sex in past year.
 - We expect that 1/3 to 1/2 may not meet eligibility criteria.
 - Randomization at Pitt: 16/24
 - Randomization at Bridge and UAB: TBD*
 - *Randomization will be over sampled to account for participant ineligible or unwillingness to participate in the IDI.
- Selection procedure at Enrollment Visit:
 - SCHARP will provide a list of randomization IDs (outside of Medidata) to indicate whether the participant is randomized to an IDI.
 - Site staff will confirm eligibility based on response to question 7 (penile-vaginal sex in past year) on DEM CRF
 - If eligible, site staff will invite participant to participate in IDI
 - Document randomization, invitation, and response on Enrollment CRF

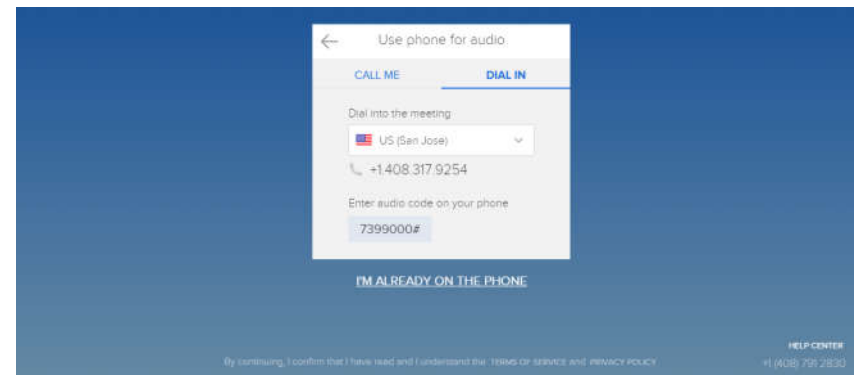
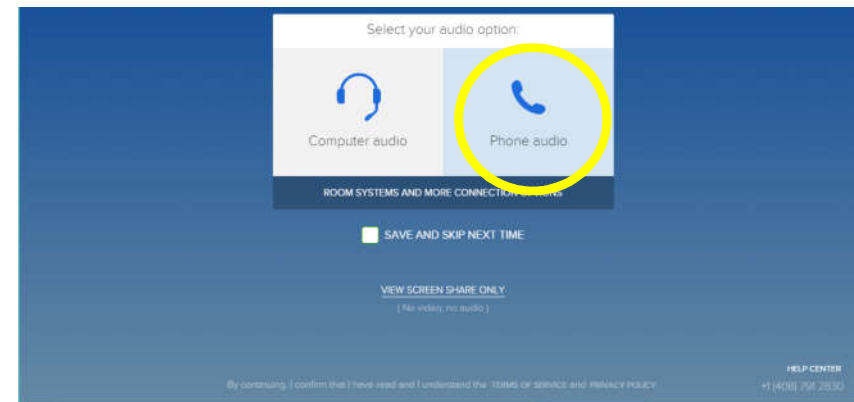
In-depth Interviews (IDIs)

- Interviewers at RTI will conduct IDI over BlueJeans
 - IDI will be audio recorded but not video recorded
- Site staff will:
 - Email interviewers and mtn038IDI@mtnstopshiv.org to notify them of scheduled interviews in advance (preferably when scheduled at Enrolment)
 - Hand **Visual Ring Comparison Tool** to participants before IDI
 - Be responsible for setting up and closing down IDI during PUEV



In-depth Interviews (IDIs)

- IDI set up:
 - Download BlueJeans (free software)
 - Quiet, private space, out of earshot
 - “Interview in Progress, Do Not Disturb” sign on door
 - Stable internet connection (supported by ethernet if necessary)
 - Webcam connected to computer
 - Landline phone next to computer
 - Connect on computer first and select “Phone audio”
 - “Dial in” or have BlueJeans call the landline
 - Ideally use headset, or speakerphone if necessary (hands should be free)
 - Comfortable space, not in front of a bright window or light (which would disturb camera)



In-depth Interviews (IDIs)

- Next steps:
 - Assemble any necessary equipment: computer, webcam (we use Logitech brand), landline, headset optional, ethernet cable
 - Schedule mock interview for site study staff with interviews to test set-up/equipment and guide soon after activation or first enrolment
- Questions? Thank you!



Questions? Thank you!