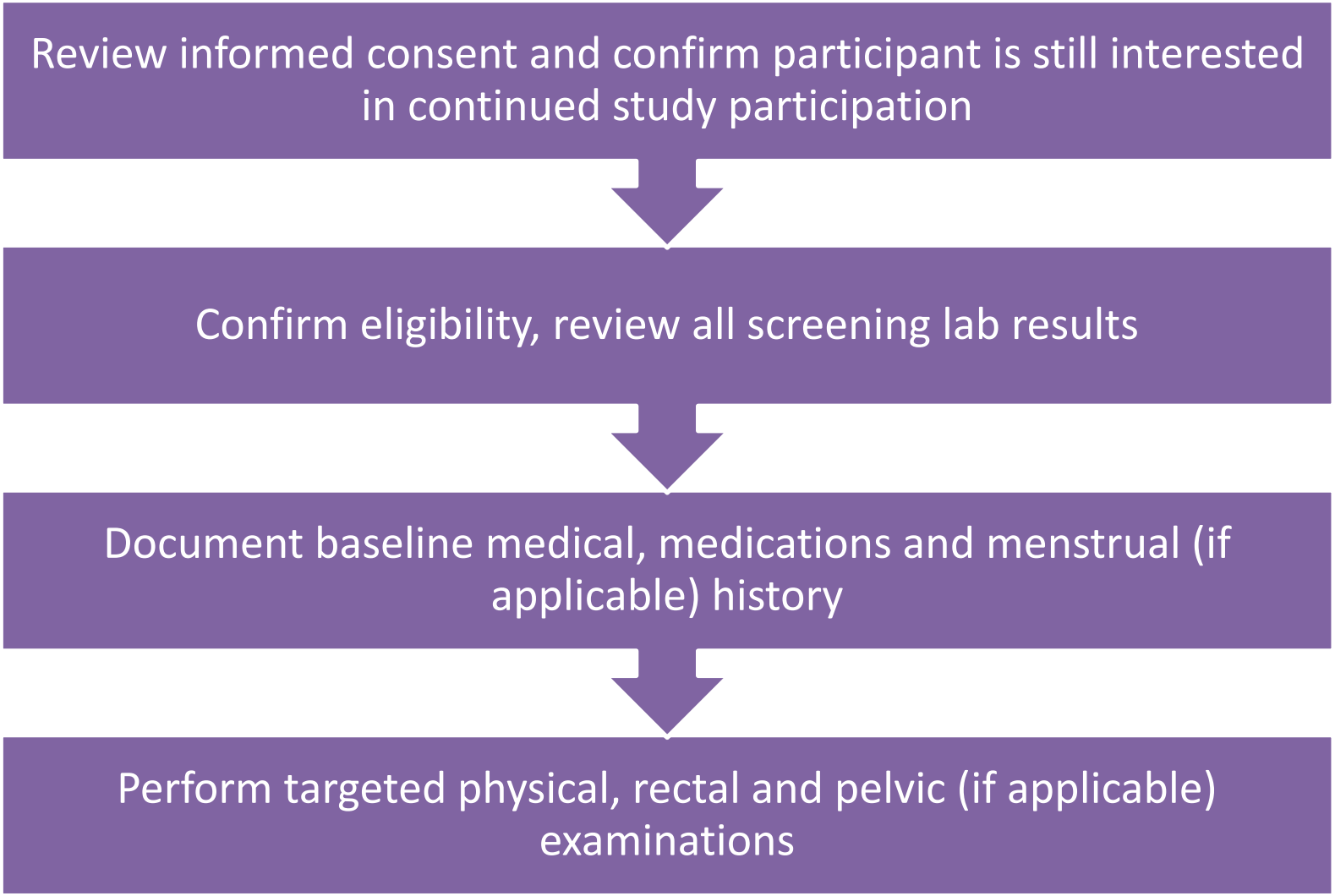
MTN-026
Enrollment considerations

Study-Specific training

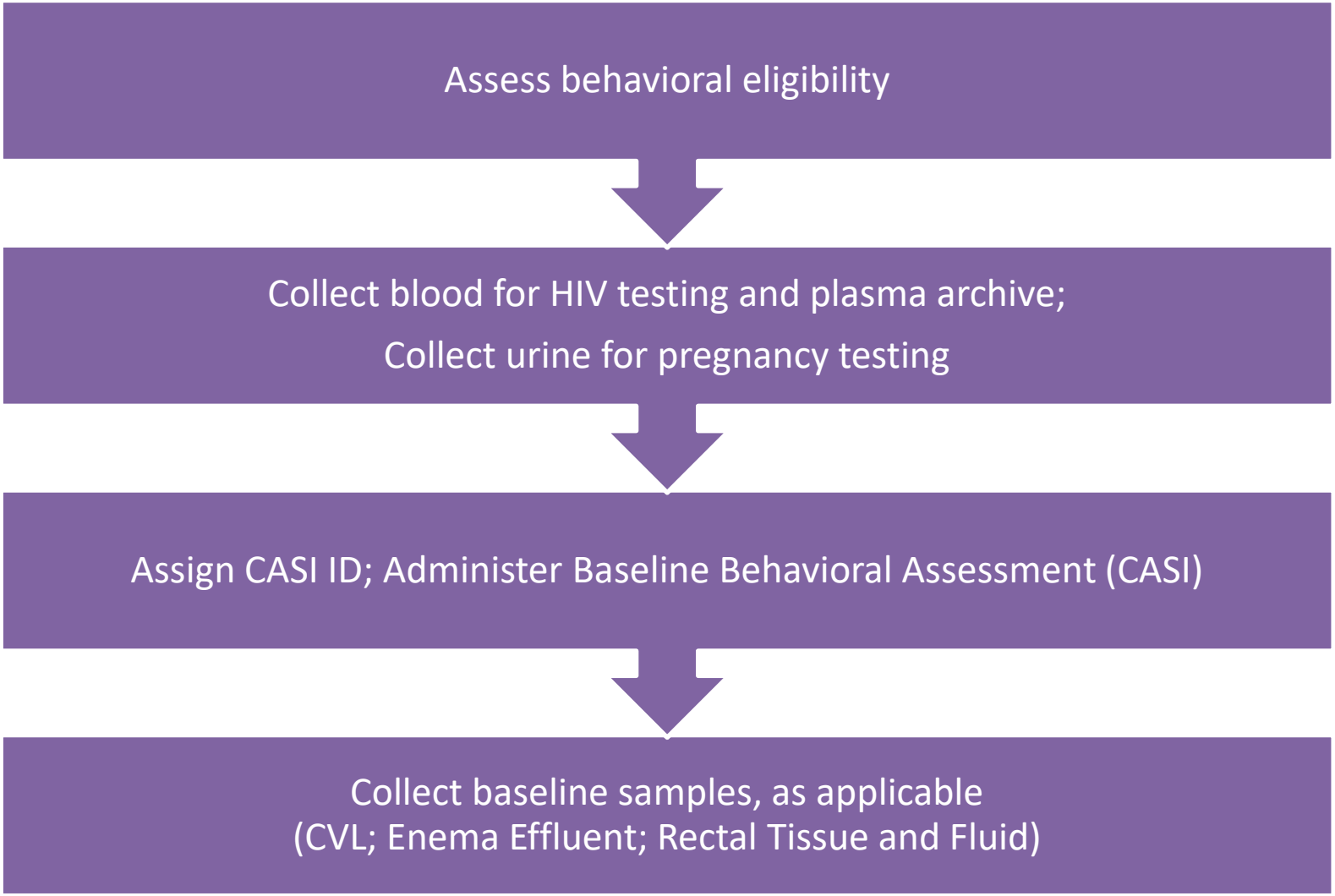
Enrollment Considerations

- The Enrollment/Visit 2 serves as the baseline visit for MTN-026.
- All procedures for this visit must be conducted on the same day.
- For female participants, menses must not coincide with enrollment visit.
  - If a participant is menstruating on the day of enrollment, her entire visit should be rescheduled for after the completion of menses, within the 45 day screening window, if possible.
- No product will be administered during the enrollment visit

Enrollment Visit



Enrollment Visit



Visit Checklist

Enrollment Visit Checklist		
	Procedures	**Staff Initials**
1.	Confirm participant identity and PTID. [Note: If female and on menses, reschedule enrollment visit within the window, if applicable]	
2.	Verify participant is within 45-day screening window. ❒ WITHIN 45 days from screening visit ==> CONTINUE. ❒ OUTSIDE 45 days from screening visit ==> STOP. Not eligible to enroll	
3.	Check for co-enrollment in other studies per site SOPs: ❒ NOT enrolled in another study ⇒ CONTINUE. ❒ Enrolled in another study ⇒ STOP. ASSESS ELIGIBILITY. CONSULT PSRT as needed	
4.	Review/update locator information and re-assess adequacy per site SOPs. ❒ Adequate locator information ==> CONTINUE. ❒ NO adequate locator information ==> STOP. NOT ELIGIBLE.	
5.	Review elements of informed consent. Explain procedures to be performed at today's visit. Confirm participant is still willing to participate and document in chart notes: ❒ Willing to participate ==> CONTINUE. ❒ NOT willing to participate==> STOP. NOT ELIGIBLE.	
6.	Provide and explain all prior screening test results.	
7.	Assess behavioral eligibility and document on **Enrollment Behavioral Eligibility Worksheet**	

Enrollment Behavioral Eligibility Worksheet

Recommended source document for assessing eligibility criteria which are based on self-report

MTN-026 Enrollment Behavioral Eligibility Worksheet
(Page 1 of 2)

PTID: ___ ___ ___-___ ___ ___ ___ ___-___ VISIT CODE: 2. 0

VISIT DATE: __ __ __ __ __ __ __

To confirm your eligibility for the study, I need to ask you a few more questions:

All Participants			
1	If you were to join this research study, are you willing to not take part in other research studies involving drugs, medical devices, genital or rectal products, or vaccines for the duration of study participation?	Yes ☐	No ☐
2	If you were to join this research study, are you able and willing to return for all study visits and comply with study participation requirements?	Yes ☐	No ☐
3	If you were to join this research study, would you be willing to be sexually abstinent for 72 hours prior to each study visit, during the study product use periods and for 72 hours after biopsy collection?	Yes ☐	No ☐
4	If you were to join this research study, would you be willing to abstain from inserting any non-study products into the rectum for 72 hours prior to each study visit, 72 hours after biopsy collection, and during the study product use periods?	Yes ☐	No ☐
5	In the past 12 months, have you used a needle to inject drugs that were not prescribed to you by a medical professional?	Yes ☐	No ☐
6	In the past 6 months have you used Post-exposure prophylaxis (PEP) for HIV exposure?	Yes ☐	No ☐

CASI ID – PTID Log

University of Alabama at Birmingham MTN-026 ID List

UAB PTID	Date (DD/MMM/YYYY)	Staff Initials

University of Pittsburgh MTN-026 ID List

Pittsburgh PTID	Date (DD/MMM/YYYY)	Staff Initials

Silom Community Clinic MTN-026 ID List

Silom PTID	Date (DD/MMM/YYYY)	Staff Initials

Eligibility Confirmation, Verification and Signatures

Once eligibility status is confirmed by reviewing and completing the Eligibility Checklist, the IoR/designee and a second staff member should sign and date the bottom of the Eligibility Checklist verifying eligibility

Final Sign-off of Participant Eligibility to Enroll:

Once a participant is deemed eligible to enroll in MTN-026, complete signatures below to confirm and verify final determination of eligibility. Only staff delegated the responsibility of primary eligibility determination per site Delegation of Authority/Staff Roster may sign for eligibility confirmation; only staff delegated the responsibility of secondary/verification of eligibility may sign for eligibility verification.

ELIGBILITY CONFIRMATION

Staff Signature: _____

Date: ___ ___ / ___ ___ ___ / ___ ___

Time: ___ ___ : ___ ___

ELIGBILITY VERIFICATION

IoR (or designee) Signature: _____

Date: ___ ___ / ___ ___ ___ / ___ ___

Time: ___ ___ : ___ ___

Randomization

On the day of Enrollment, participants will be assigned to:

- Time assignment:
  - PK/PD sample collection
  - 30-60 minutes or 120 minutes
  - Visit 3 and 13 (Dosing Visits)

- Day assignment:
  - PK/PD sample collection
  - 24, 48, or 72 hours after Dosing Visits 3 and 13

Note: assignment done at enrollment will be maintained throughout the study.

Example of Randomization Assignment…

- If, at Enrollment, a participant is assigned to the following PK/PD timepoints:
  - Collection of genital samples at 120 minutes (2 hours) after gel is administered at Visit 3
  - Collection of genital samples 48 hours post gel administration at Visit 5, samples
- When will s/he have genitals samples collected again?
  - Collection will occur again at Visit 13 (2 hours) after gel is administered
  - Collection will occur at Visit 15 (48 hours post Visit 13). Note, a sample collection allowable window of +/-2 hours has been established for this visit. To be discussed later.

To be discussed later…

- Randomization will be done in Medidata Balance; procedures will be covered during the SCHARP presentation.

- Study Product Dispensation Documentation (Prescription, Accountability Logs), and Chain of Custody Procedures will be covered during Study Product Considerations section of the agenda.

Randomization is the act of enrollment into MTN-026. Notify the Management Team and PSRT if ineligible participant has inadvertently been enrolled in the study

Post-randomization Procedures

- Provision of study product instructions
- Provision of site contact information
- Reimbursement
- Schedule next visit
- Generate and provide follow-up visit schedule

Screening and Enrollment Log

No.	Screening Date DD-MMM-YY	Screening Attempt (1 or 2)	PTID	Date Enrollment window closes DD-MMM-YY	Staff Initials / Date DD-MMM-YY	Enrollment Date (not enrolled: NA) DD-MMM-YY	Screen Failure Date (enrolled: NA) DD-MMM-YY	Screening Failure Codes (enrolled: NA) DD-MMM-YY	Staff Initials / Date DD-MMM-YY

Screen Failure Codes

I1	Not 18-45 (inclusive)	I10	Unwilling to abstain from use of non-study products in rectum (72 hrs)	E1iii	WBC grade 2 or higher	E4	PEP within 6 months	E12	Diagnosed RTI/STI/UTI at Enrollment
I2	Not able to provide IC			E1iv	Serum creatinine >1.3x site lab ULN	E5	PrEP within 6 months or anticipated use	E13	Any other condition (IoR/designee)
I3	HIV positive	I11	Females: Unsatisfactory Pap, ≥21 years of age	E1v	INR >1.5x site lab ULN	E6	Systemic Immunomodulatory Meds within 6 months or anticipated use		
I4	Inadequate locator info.	I12	Females: Unwilling to be abstinent (72hrs/7days)	E1vi	AST or ALT grade 1 or higher			E14	Females: Pregnant or Breastfeeding
I5	Noncompliance w/ study requirements	I13	Females: Unwilling to abstain from use of non-study products in vagina (72hrs/7days)	E1vii	Hepatitis C positive	E7	Unprotected sex with known HIV+ partner within 6 months	E15	Females: Last pregnancy within 90 days
I6	Not in good general health			E1viii	Hepatitis B Surface Antigen positive	E8	IV drug use within 12 months	E16	Females: Had hysterectomy
I7	No history of RAI within past year	I14	Females: No contraception	E1ix	History of inflammatory bowel disease	E9	Participation in a study within 45 days	E17	Females: Pelvic finding grade 1 or higher
I8	May participate in other studies	E1i	Hemoglobin grade 1 or higher	E2	Anticipated/use of prohibited medication	E10	Treated for anogenital STI within 3 months		
I9	Unwilling to be abstinent (72hrs)	E1ii	Platelet count grade 1 or higher	E3	Known allergy to study product	E11	Diagnosed RTI/STI/UTI at Screening		

Questions? Comments?