Form: Informed Consent

Informed consent date	_____
Did the participant consent to long-term specimen storage?	Yes ☐ No ☐

Form: Demographics

Date of birth _____

Age Fixed Unit: yrs

_____

Ethnicity

- Hispanic or Latino ☐
- Not Hispanic or Latino ☐
- Not reported ☐
- Unknown ☐

Race

Mark all that apply.

- American Indian or Alaska Native ☐
- Asian ☐
- Black or African American ☐
- Native Hawaiian or other Pacific Islander ☐
- White ☐
- Other race ☐
- Other race, please specify: _____

What is the participant's current gender identity?

Mark all that apply.

- Man ☐
- Woman ☐
- Cisgender Man ☐
- Cisgender Woman ☐
- Transgender Man/Trans Man ☐
- Transgender Woman/Trans Woman ☐
- Gender Non-conforming, Gender Non-binary ☐
- Genderqueer ☐
- Two-Spirit ☐
- Additional identity, please specify: _____
- Decline to answer ☐

How do you identify your sexual orientation?

- Bisexual ☐
- Gay/Lesbian/Homosexual/Same-Gender Loving ☐
- Pansexual ☐
- Queer ☐
- Straight/Heterosexual ☐
- Two Spirit ☐

Form: Demographics

	Additional identity ☐
	Not sure ☐
	Prefer not to answer ☐
If "Additional identity", specify:	_____
How do you define your relationship status?	I am single ☐
	I am casually dating ☐
	I have a boyfriend or girlfriend ☐
	I have a partner or lover ☐
	Although we lack a legal commitment, I am with a partner and we have had a commitment ceremony ☐
	I am in a civil union or domestic partnership ☐
	I am legally married ☐
	Other relationship status ☐
If "Other relationship status", specify:	_____
What is your current occupational status? Mark all that apply.	
Full time work	☐
Part time work	☐
In school full or part time	☐
Neither work nor in school	☐
On disability	☐
Other occupational status, specify:	_____
During the last 12 months, what was your total personal income from all sources?	$10,000 or less ☐
	$10,001 to $20,000 ☐
	$20,001 to $40,000 ☐
	$40,001 to $60,000 ☐
	$60,001 to $80,000 ☐
	Over $80,000 ☐
	Don't know ☐
What kind of residence do you live in?	Single family home ☐
	Apartment ☐
	Boarding house ☐
	Dormitory ☐
	Shelter ☐
	Other residence ☐
If "Other residence", specify:	_____

Form: Demographics

With whom do you live?

Mark all that apply.

No one, I live alone	☐
Parents	☐
Siblings	☐
Friends	☐
Roommates	☐
Spouse	☐
Significant other(s) (ie, partner, lover, boyfriend, etc)	☐
Other, specify:	_____

Form: Date of Visit

Did the participant complete this visit?	Yes ☐ No ☐
This section is required if the participant completed the visit.	
What was the visit date?	_____
Mark if procedures done at this visit were conducted outside of the visit window with protocol-specified approval	☐
This section is required if the participant did not complete the visit.	
What was the reason the visit was missed? If participant withdrew from study, complete Study Termination form. If "Death", complete Study Termination form and Adverse Event log.	Unable to contact participant ☐ Participant unable to schedule visit within window ☐ Participant refused visit ☐ Participant incarcerated ☐ Participant admitted to healthcare facility ☐ Death ☐ Other ☐
If "Other", specify:	_____
This section is required for both completed and not completed visits.	
Is the study product administration schedule being discontinued within this visit window? If "Yes", complete Discontinuation of Study Product Administration form.	Yes ☐ No ☐
Did the participant exit/terminate the study within this visit window? If "Yes", complete Study Termination form.	Yes ☐ No ☐
ADDITIONAL PROCEDURES/FORMS	
Chemistry Panel	☐
Hematology	☐
Participant Receipt	☐
Participant Transfer	☐
Physical Examination	☐
Product Dispensation and Returns	☐
STI Test Results	☐
Vital Signs	☐

Form: Interim Visit

Interim visit code	_____
Date of visit	_____
What is/are the reason(s) for this interim visit?Mark all that apply.	
Participant is missing part or all of a scheduled study visit and is outside of the visit window	☐
Participant contacted site to report adverse event(s) Update the Adverse Event log.	☐
Repeat specimen collection	☐
Follow-up of abnormal safety assessment	☐
Interim HIV testing (not due to redraw request)	☐
Redraw for HIV testing requested by Regional Network HIV Diagnostics Laboratory	☐
Social Impact Update Social Impact log as appropriate.	☐
Product Dispensation or Returns	☐
Other reason	☐
If "Other reason", specify (max. 200 characters):	_____
Did the participant exit/terminate the study at this visit?	Yes ◯
If "Yes", complete the Termination form.	No ◯
FORMS COMPLETED AT INTERIM VISIT:	
Chemistry Panel	☐
Hematology	☐
HIV Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Physical Examination	☐
Product Dispensation and Returns	☐
Specimen Collection	☐
STI Test Results	☐
Vital Signs	☐

Form: Screening Outcome

Has the participant screened before?	Yes ☐ No ☐
Enter the first RAVE PTID assigned	_____
Eligibility status If "Incomplete screening", end of form.	Eligible and enrolled ☐ Eligible/Not enrolled ☐ Ineligible ☐ Incomplete Screening ☐

COMPLETE THIS SECTION FOR ENROLLED PARTICIPANTS.

Is this participant enrolling in the PK/PD sub-study?	Yes ☐ No ☐
Biopsy day assignment	Biopsy Day 1 ☐ Biopsy Day 2 ☐ Biopsy Day 4 ☐ Biopsy Day 8 ☐

COMPLETE THIS SECTION FOR ELIGIBLE/NOT ENROLLED OR INELIGIBLE PARTICIPANTS.

Date participant was found "Eligible/Not Enrolled" or "Ineligible"	_____
Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible".	Was not assigned male sex at birth ☐ Wasn't at least 18 years of age or older ☐ Wasn't willing and able to provide informed consent ☐ Wasn't able to read at a level required for the study components ☐ Doesn't have access to device and the internet for completion of study procedures ☐ Doesn't understand or agree to local STI reporting requirements ☐ Does not have a history of consensual RAI at least five times in their lifetime and at least once in the prior 3 months ☐ Has not received or self-administered an enema or rectal douche more than half the time prior to engaging in RAI in the past year ☐ Is not willing and able to use condoms for all sexual intercourse for the duration of participation ☐ Does not agree to not participate in other research studies as outlined in the protocol ☐ Is not willing and able to provide adequate locator information ☐

Form: Screening Outcome

- [ ] Does not agree to not engage in receptive or insertive sexual activity with another study participant
- [ ] Is not available to return for all study visits and within any site's catchment area
- [ ] A reactive/positive HIV test at screening or at least one reactive/positive test result at enrollment
- [ ] A history of active hepatitis B virus infection, as documented by positive HBV surface antigen at screening
- [ ] Co-enrollment in any other interventional research study that may interfere with this study
- [ ] Grade 2 or above laboratory abnormality at baseline
- [ ] Significant colorectal symptom(s) as determined by medical history or by participant self-report
- [ ] Symptoms and/or clinical or laboratory diagnosis of active rectal or reproductive tract infection requiring treatment
- [ ] History of an underlying clinically significant cardiac arrhythmia or renal disease
- [ ] History of severe or recent cardiac or pulmonary event
- [ ] History of significant gastrointestinal bleeding
- [ ] Use of F/TDF or use of F/TAF as HIV PrEP within 8 weeks prior to screening visit or anticipated use throughout study participation
- [ ] Use of injectable PrEP within 8 weeks prior to the screening visit or anticipated use throughout study participation
- [ ] Use of protocol exclusionary medication or product
- [ ] Known allergic reaction to TFV or other components of the test articles
- [ ] Current known partners with HIV, unless with sustained viral suppression on antiretroviral treatment
- [ ] History of recurrent urticaria
- [ ] Symptoms suggestive of acute HIV infection
- [ ] Individual changed their mind
- [ ] Unable to contact/no show

Form: Screening Outcome

	Investigator decision ☐
If "Investigator decision", specify (max. 200 characters):	_____

Form: Adverse Event Log Line #_____

Date AE reported to site	_____
Adverse event (AE)	_____
Onset date	_____
At which visit was this adverse event first reported?	V1.0 - Screening ☐
	V2.0 - Enrollment - Start Period 1 ☐
	V201.0 - Period 1 - Day 1 ☐
	V202.0 - Period 1 - Day 2 ☐
	V203.0 - Period 1 - Day 4 ☐
	V204.0 - Period 1 - Day 8 ☐
	V3.0 - Mid Period 1 ☐
	V4.0 - End Period 1 ☐
	V5.0 - Start Period 2 ☐
	V501.0 - Period 2 - Day 1 ☐
	V502.0 - Period 2 - Day 2 ☐
	V503.0 - Period 2 - Day 4 ☐
	V504.0 - Period 2 - Day 8 ☐
	V6.0 - Mid Period 2 ☐
	V7.0 - End Period 2 ☐
	V8.0 - Health Contact ☐
	Interim visit ☐
If "Interim visit", specify interim visit code.	_____
Is the AE still ongoing?	Yes ☐
	No ☐
If "No", outcome date	_____
Severity grade	Grade 1 (Mild) ☐
	Grade 2 (Moderate) ☐
	Grade 3 (Severe) ☐
	Grade 4 (Potentially life-threatening) ☐
	Grade 5 (Death) ☐
Relationship to rectal biopsy procedure	Related ☐
	Not related ☐
Relationship to study product application (e.g. douching process)	Related ☐
	Not related ☐
Relationship to study product	Related ☐
	Not related ☐
Record pertinent details for relationship assessment in "Comments".	
Action taken with study product	Dose not changed ☐
	Drug withdrawn ☐

Form: Adverse Event Log Line #_____

	Drug interrupted ☐
	Not applicable ☐
Other actions Mark "None" or all that apply.	☐
None	
Medication(s)	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Other	☐
If "Other", specify (max. 200 characters):	_____
Status/Outcome If "Severity/Frequency increased" is selected, report as a new adverse event.	Recovered/Resolved ☐ Recovering/Resolving ☐ Recovered/Resolved with Sequelae ☐ Not recovered/Not resolved ☐ Fatal ☐ Severity/Frequency increased ☐
If status or outcome is "Severity/Frequency increased", select adverse event.	_____
Is this a serious adverse event according to ICH/GCP or protocol guidelines? If "No", go to "Has or will this AE be reported as an SAE/EAE?". If "Yes", check all that apply.	Yes ☐ No ☐
Results in death	☐
Is life-threatening	☐
Requires inpatient hospitalization or prolongation of existing hospitalization	☐
Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
Has or will this AE be reported as an EAE? If "Yes", provide EAE number below.If "No", go to "Was this AE a worsening of a baseline medical condition?".	Yes ☐ No ☐
SAE/EAE number Begin number with 4-digit year, followed by 6-digit SAE/EAE number (no dashes or spaces).	_____

Form: Adverse Event Log Line #_____

SAE/EAE onset date	_____
Was this AE a worsening of a baseline medical condition?	Yes ☐ No ☐
Comments (max. 450 characters):	_____

Form: Anorectal Exam

Was an anorectal exam performed?	Yes ◯ No ◯
Anorectal exam date	_____

ANOSCOPY

Rectal mucosa findings	Not done ◯ No abnormal findings ◯ Abnormal findings ◯

If "Abnormal findings", select all that apply.

Erythema	☐
Abnormal vessels	☐
Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If "Other abnormal findings", specify (max. 200 characters):	_____

SIGMOIDOSCOPY

Sigmoidoscopy findings	Not done ◯ No abnormal findings ◯ Abnormal findings ◯

If "Abnormal findings", select all that apply.

Erythema	☐
Abnormal vessels	☐
Ulceration	☐
Friability	☐
Bleeding	☐
Discharge	☐
Polyps	☐
Hemorrhoids	☐
Other abnormal findings	☐
If "Other abnormal findings", specify (max. 200 characters)::	_____

Form: CASI Tracking

CASI collection date	_____
Which questionnaire was completed?	Enrollment ☐ Week 8 - End Period 1 ☐ Week 18 - End Period 2 ☐
Were there any problems or issues related to the administration or completion of the questionnaire?	Yes ☐ No ☐
If "Yes", please describe.	_____

Form: Chemistry Panel

Was a sample collected for serum chemistries?	Yes ☐ No ☐
Specimen collection date	
LIVER FUNCTION TESTS	
AST (SGOT)	
AST (SGOT) severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
AST (SGOT) adverse event	
AST not reportable as an adverse event	☐
ALT (SGPT)	
ALT (SGPT) severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
ALT (SGPT) adverse event	
ALT not reportable as an adverse event	☐
RENAL FUNCTION TESTS	
Creatinine	
Creatinine severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Creatinine adverse event	
Creatinine not reportable as an adverse event	☐
BUN	
eGFR	
eGFR severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
eGFR adverse event	

Form: Chemistry Panel

eGFR not reportable as an adverse event	☐
Comments (max. 200 characters):	

Form: Concomitant Medications Log Line #_____

Medication name _____

Indication _____

Date started _____

Date stopped

Or _____

Ongoing ☐

Dose _____

Dose units

- ☐ Grams
- ☐ Micrograms
- ☐ Milligrams
- ☐ Milliliters
- ☐ Capsules
- ☐ Drops
- ☐ Puffs
- ☐ Sachets
- ☐ Suppository
- ☐ Tablets
- ☐ Units
- ☐ Unknown
- ☐ Other

If "Other", specify: _____

Frequency

- ☐ As needed
- ☐ Daily
- ☐ Twice per day
- ☐ Three times per day
- ☐ Four times per day
- ☐ At hour of wake
- ☐ At hour of sleep
- ☐ Once
- ☐ Other

If "Other", specify: _____

Route

- ☐ Oral
- ☐ Intramuscular
- ☐ Intravenous
- ☐ Topical
- ☐ Inhalation
- ☐ Vaginal
- ☐ Rectal

Form: Concomitant Medications Log Line #_____

	Subcutaneous ☐
	Other ☐
If "Other", specify:	_____
Taken for a reported AE?	Yes ☐
	No ☐
If "Yes", select adverse event.	_____

Form: Day 1 PK Specimen Collection and Storage

Specimen type	Pre-dose Plasma day 1 ■
	Pre-dose PBMC day 1 ☐
	Post-dose Plasma day 1:1 hour ☐
	Post-dose PBMC day 1:1 hour ☐
	Post-dose Plasma day 1:3 hour ☐
	Post-dose PBMC day 1:3 hour ☐
	Post-dose Plasma day 1:6 hour ☐
	Post-dose PBMC day 1:6 hour ☐
	Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	_____
Specimen collection date	_____
Specimen collection time	_____
Was sample stored?	Stored ☐
	Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	_____

Specimen type	Pre-dose Plasma day 1 ☐
	Pre-dose PBMC day 1 ■
	Post-dose Plasma day 1:1 hour ☐
	Post-dose PBMC day 1:1 hour ☐
	Post-dose Plasma day 1:3 hour ☐
	Post-dose PBMC day 1:3 hour ☐
	Post-dose Plasma day 1:6 hour ☐
	Post-dose PBMC day 1:6 hour ☐
	Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	_____
Specimen collection date	_____
Specimen collection time	_____
Was sample stored?	Stored ☐
	Not stored ☐

Form: Day 1 PK Specimen Collection and Storage

If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Pre-dose Plasma day 1 ☐
	Pre-dose PBMC day 1 ☐
	Post-dose Plasma day 1:1 hour ☐
	Post-dose PBMC day 1:1 hour ☐
	Post-dose Plasma day 1:3 hour ☐
	Post-dose PBMC day 1:3 hour ☐
	Post-dose Plasma day 1:6 hour ☐
	Post-dose PBMC day 1:6 hour ☐
	Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐
	Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Pre-dose Plasma day 1 ☐
	Pre-dose PBMC day 1 ☐
	Post-dose Plasma day 1:1 hour ☐
	Post-dose PBMC day 1:1 hour ☐
	Post-dose Plasma day 1:3 hour ☐
	Post-dose PBMC day 1:3 hour ☐
	Post-dose Plasma day 1:6 hour ☐
	Post-dose PBMC day 1:6 hour ☐
	Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐

Form: Day 1 PK Specimen Collection and Storage

	Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Pre-dose Plasma day 1 ☐
	Pre-dose PBMC day 1 ☐
	Post-dose Plasma day 1:1 hour ☐
	Post-dose PBMC day 1:1 hour ☐
	Post-dose Plasma day 1:3 hour ☐
	Post-dose PBMC day 1:3 hour ☐
	Post-dose Plasma day 1:6 hour ☐
	Post-dose PBMC day 1:6 hour ☐
	Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐
	Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Pre-dose Plasma day 1 ☐
	Pre-dose PBMC day 1 ☐
	Post-dose Plasma day 1:1 hour ☐
	Post-dose PBMC day 1:1 hour ☐
	Post-dose Plasma day 1:3 hour ☐
	Post-dose PBMC day 1:3 hour ☐
	Post-dose Plasma day 1:6 hour ☐
	Post-dose PBMC day 1:6 hour ☐
	Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	

Form: Day 1 PK Specimen Collection and Storage

Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	_____
Specimen type	Pre-dose Plasma day 1 ☐ Pre-dose PBMC day 1 ☐ Post-dose Plasma day 1:1 hour ☐ Post-dose PBMC day 1:1 hour ☐ Post-dose Plasma day 1:3 hour ☐ Post-dose PBMC day 1:3 hour ☐ Post-dose Plasma day 1:6 hour ■ Post-dose PBMC day 1:6 hour ☐ Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐ No ☐ Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	_____
Specimen collection date	_____
Specimen collection time	_____
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	_____
Specimen type	Pre-dose Plasma day 1 ☐ Pre-dose PBMC day 1 ☐ Post-dose Plasma day 1:1 hour ☐ Post-dose PBMC day 1:1 hour ☐ Post-dose Plasma day 1:3 hour ☐ Post-dose PBMC day 1:3 hour ☐ Post-dose Plasma day 1:6 hour ☐ Post-dose PBMC day 1:6 hour ■ Pre-dose Rectal swabs ☐
Was specimen collected?	Yes ☐ No ☐ Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	_____
Specimen collection date	_____

Form: Day 1 PK Specimen Collection and Storage

Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Pre-dose Plasma day 1 ☐ Pre-dose PBMC day 1 ☐ Post-dose Plasma day 1:1 hour ☐ Post-dose PBMC day 1:1 hour ☐ Post-dose Plasma day 1:3 hour ☐ Post-dose PBMC day 1:3 hour ☐ Post-dose Plasma day 1:6 hour ☐ Post-dose PBMC day 1:6 hour ☐ Pre-dose Rectal swabs ■
Was specimen collected?	Yes ☐ No ☐ Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Form: Directly Observed Therapy

Date of observed therapy	
Time of observed therapy completion	
Number of tablets taken in the office If "none", enter "0".	
Number of medicated sachets administered in the office If "none", enter "0".	
Number of water douches administered in the office If "none", enter "0".	
Were there any deviations during the directly observed therapy?	Yes ☐ No ☐
If "yes", explain the deviation.	

Form: Discontinuation of Study Product

Which study product is being discontinued?	TFV Douche ☐ F/TDF Tablet ☐
Date that study product use ended	_____
Primary reason for ending study product use	Scheduled study product use period completed ☐ Death ☐ Participant refused further participation ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Participant refused further study product use ☐ HIV infection ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ One or more reactive HIV test results or acute HIV infection suspected ☐ Participant unable to adhere to visit schedule ☐ Report of use of prohibited concomitant medications ☐ Participant incarcerated ☐ Other ☐
If "Other", specify (max. 200 characters):	_____
If "Adverse event" or "Death", select applicable adverse event.	_____
Will the participant resume the same study product?	Yes ☐ No ☐
Date participant resumed the same study product	_____

Form: Enema Tip Collection

Date enema tip received at site	_____
Date of enema tip use	_____
Where was enema tip testing performed?	On site ☐
	At the LLC ☐
Date of enema tip testing	_____
Testing results	Not done ☐
	Negative ☐
	Positive ☐
	Invalid ☐
	Indeterminate ☐

Form: Hematology

HEMOGRAM	
Was a hematology sample collected?	Yes ☐ No ☐
Hematology collection date	
Hemoglobin	
Hemoglobin severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Hemoglobin adverse event, if applicable	
Hemoglobin not reportable as an adverse event	☐
Hematocrit	
MCV	
Platelets	
Platelets severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Platelets adverse event, if applicable	
Platelets not reportable as an adverse event	☐
WBC	
WBC severity grade	Not gradable ☐ Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
WBC adverse event, if applicable	
WBC not reportable as an adverse event	☐
Comments (max. 200 characters):	

Form: HIV Test Results

Was HIV testing performed?	Yes ☐ No ☐
HIV RAPID TEST	
HIV-1 Rapid specimen collection date	_____
HIV-1 Rapid Results	Non-reactive ☐ Reactive/Positive ☐ Not done ☐
HIV LABORATORY BASED TESTING	
HIV laboratory based testing specimen collection date	_____
HIV EIA or CMIA	Non-reactive ☐ Reactive/Positive ☐ Not done ☐
HIV 1/2 Discriminatory Assay Result	Assay result not provided ☐ HIV Negative ☐ HIV-1 Positive ☐ HIV-2 Positive ☐ HIV-2 Positive with HIV-1 Cross-Reactivity ☐ HIV-1 Positive, Untypable ☐ HIV-1 Indeterminate ☐ HIV-2 Indeterminate ☐ HIV Indeterminate ☐ Not done ☐ Other ☐
If "Other", specify:	_____
HIV-1 RNA	Non-reactive/Not detected ☐ Reactive/Detected ☐ Not done ☐
FINAL HIV STATUS	
Final HIV status	Negative ☐ Positive ☐ Additional testing needed ☐

Form: Medical History

Log Line #_____

Date medical history collected	_____
Description of medical history condition/event	_____
Is condition/event gradable?	Yes ☐ No ☐
Severity grade	Grade 1 (Mild) ☐ Grade 2 (Moderate) ☐ Grade 3 (Severe) ☐ Grade 4 (Potentially life-threatening) ☐
Start date of medical history condition/event	_____
Is the condition ongoing?	Yes ☐ No ☐
Date medical history/condition ended/resolved	_____
Comments (max. 200 characters):	_____

Form: Mucosal Biopsy Collection - Rectal

Specimen collection date	_____
Were dry biopsies collected?	Collected ☐
If "Not Collected", go to "Were wet biopsies collected?"	Not Collected ☐
How many dry biopsies were collected? (5 required at visit)	_____
Were wet biopsies collected?	Collected ☐
If "Not Collected", go to "If any of the 14 required biopsies were not collected..."	Not Collected ☐
How many wet biopsies were collected? (9 required at visit)	_____

If any of the 14 required biopsies were not collected, select the reason(s) below.

Reason-1	Another rectal biopsy in the past 21 days ☐
	Bleeding from biopsy sites excessive ☐
	Clinician decision ☐
	Clinician decision that participant did not tolerate the procedure well ☐
	Clinician unavailable to collect samples ☐
	Compensation not adequate ☐
	Difficult to visualize biopsy site ☐
	Difficulty with insertion or removal of the device ☐
	Discomfort due to the anoscope ☐
	Embarrassment or emotional discomfort with rectal collection ☐
	Fever or other illness ☐
	Hemmorrhoids ☐
	Menstruation ☐
	Participant concerned about ability to get pregnant ☐
	Participant concerned about increased susceptibility to HIV or an STI after the procedure ☐
	Participant concerned about risks and complications from the procedure ☐
	Participant concerned about what is done with the sample ☐
	Partner or family disapproval ☐
	Positive STI test results ☐
	Pregnancy ☐
	Procedures too time consuming ☐
	Protocol Team Decision ☐
	Rectal biopsy pain or discomfort (can happen during or after biopsy) ☐
	Risk for HIV has increased since last visit ☐

Form: Mucosal Biopsy Collection - Rectal

	Site could not process specimens ☐ Site or participant did not have required supplies ☐ Too invasive ☐ Tool malfunction ☐ Unprotected receptive anal sex 48 hours before the visit ☐ Unwilling to abide by sexual abstinence after the collection of samples ☐ Unwilling to provide biopsy specimens ☐ Use of anticoagulants ☐ Use of antithrombotic medication ☐ Other ☐
Reason-2	Another rectal biopsy in the past 21 days ☐ Bleeding from biopsy sites excessive ☐ Clinician decision ☐ Clinician decision that participant did not tolerate the procedure well ☐ Clinician unavailable to collect samples ☐ Compensation not adequate ☐ Difficult to visualize biopsy site ☐ Difficulty with insertion or removal of the device ☐ Discomfort due to the anoscope ☐ Embarrassment or emotional discomfort with rectal collection ☐ Fever or other illness ☐ Hemmorrhoids ☐ Menstruation ☐ Participant concerned about ability to get pregnant ☐ Participant concerned about increased susceptibility to HIV or an STI after the procedure ☐ Participant concerned about risks and complications from the procedure ☐ Participant concerned about what is done with the sample ☐ Partner or family disapproval ☐ Positive STI test results ☐ Pregnancy ☐ Procedures too time consuming ☐

Form: Mucosal Biopsy Collection - Rectal

	Protocol Team Decision ☐
	Rectal biopsy pain or discomfort (can happen during or after biopsy) ☐
	Risk for HIV has increased since last visit ☐
	Site could not process specimens ☐
	Site or participant did not have required supplies ☐
	Too invasive ☐
	Tool malfunction ☐
	Unprotected receptive anal sex 48 hours before the visit ☐
	Unwilling to abide by sexual abstinence after the collection of samples ☐
	Unwilling to provide biopsy specimens ☐
	Use of anticoagulants ☐
	Use of antithrombotic medication ☐
	Other ☐
Reason-3	Another rectal biopsy in the past 21 days ☐
	Bleeding from biopsy sites excessive ☐
	Clinician decision ☐
	Clinician decision that participant did not tolerate the procedure well ☐
	Clinician unavailable to collect samples ☐
	Compensation not adequate ☐
	Difficult to visualize biopsy site ☐
	Difficulty with insertion or removal of the device ☐
	Discomfort due to the anoscope ☐
	Embarrassment or emotional discomfort with rectal collection ☐
	Fever or other illness ☐
	Hemmorrhoids ☐
	Menstruation ☐
	Participant concerned about ability to get pregnant ☐
	Participant concerned about increased susceptibility to HIV or an STI after the procedure ☐
	Participant concerned about risks and complications from the procedure ☐
	Participant concerned about what is done with the sample ☐

Form: Mucosal Biopsy Collection - Rectal

	Partner or family disapproval ☐
	Positive STI test results ☐
	Pregnancy ☐
	Procedures too time consuming ☐
	Protocol Team Decision ☐
	Rectal biopsy pain or discomfort (can happen during or after biopsy) ☐
	Risk for HIV has increased since last visit ☐
	Site could not process specimens ☐
	Site or participant did not have required supplies ☐
	Too invasive ☐
	Tool malfunction ☐
	Unprotected receptive anal sex 48 hours before the visit ☐
	Unwilling to abide by sexual abstinence after the collection of samples ☐
	Unwilling to provide biopsy specimens ☐
	Use of anticoagulants ☐
	Use of antithrombotic medication ☐
	Other ☐
If any Reason code selected is "Other" or "Clinician decision", specify:	_____
Procedure Details	
Time endoscopy procedure began	_____
Time endoscopy procedure ended	_____
Were any rectal biopsy collection-related adverse events observed?	Yes ☐
If "Yes", select associated adverse event.	No ☐
Adverse event	_____
Comments (max. 200 characters):	_____

Form: Participant Receipt

Name of receiving study site	☐ University of Alabama at Birmingham ☐ University of Pittsburg ☐ UNC Chapel Hill ☐ UCLA CARE Center ☐ The Hope Clinic ☐ The Fenway Institute ☐ Weill Cornell Chelsea ☐ John Hopkins University
Name of transferring study site	☐ University of Alabama at Birmingham ☐ University of Pittsburg ☐ UNC Chapel Hill ☐ UCLA CARE Center ☐ The Hope Clinic ☐ The Fenway Institute ☐ Weill Cornell Chelsea ☐ John Hopkins University
Date Participant Received at Receiving Site	_____
Date Informed Consent was signed at Receiving Study Site	_____

Form: Participant Transfer

Name of transferring study site	☐ University of Alabama at Birmingham ☐ University of Pittsburg ☐ UNC Chapel Hill ☐ UCLA CARE Center ☐ The Hope Clinic ☐ The Fenway Institute ☐ Weill Cornell Chelsea ☐ John Hopkins University
Name of receiving study site	☐ University of Alabama at Birmingham ☐ University of Pittsburg ☐ UNC Chapel Hill ☐ UCLA CARE Center ☐ The Hope Clinic ☐ The Fenway Institute ☐ Weill Cornell Chelsea ☐ John Hopkins University
Visit of last completed contact with participant	☐ V1.0 - Screening ☐ V2.0 - Enrollment - Start Period 1 ☐ V201.0 - Period 1 - Day 1 ☐ V202.0 - Period 1 - Day 2 ☐ V203.0 - Period 1 - Day 4 ☐ V204.0 - Period 1 - Day 8 ☐ V3.0 - Mid Period 1 ☐ V4.0 - End Period 1 ☐ V5.0 - Start Period 2 ☐ V501.0 - Period 2 - Day 1 ☐ V502.0 - Period 2 - Day 2 ☐ V503.0 - Period 2 - Day 4 ☐ V504.0 - Period 2 - Day 8 ☐ V6.0 - Mid Period 2 ☐ V7.0 - End Period 2 ☐ V8.0 - Health Contact ☐ Interim visit
If "Interim visit", specify Interim visit code	_____
Date participant's records were sent to receiving study site	_____

Form: Physical Exam

Was a physical exam performed?	Yes ☐ No ☐
Date of exam	_____
BODY SYSTEM	
HEENT	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Neck	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Lymph Nodes	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Heart/Cardiovascular	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Lung/Respiratory	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Abdomen	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Genitourinary	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Extremities	Not done ☐ Normal ☐ Abnormal ☐
If "Abnormal", specify:	_____
Neurological	Not done ☐ Normal ☐

Form: Physical Exam

	Abnormal ☐
If "Abnormal", specify:	_____
Skin	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
General appearance	Not done ☐
	Normal ☐
	Abnormal ☐
If "Abnormal", specify:	_____
Other system finding	Not done ☐
	Normal ☐
	Abnormal ☐
If "Other system", specify system:	_____
If "Abnormal", specify:	_____
Comments (max. 200 characters):	_____

Form: PK Specimen Collection and Storage

Specimen type	Plasma for PK ■ PBMC for PK ☐ Rectal swabs for lab ☐
Was specimen collected?	Yes ☐ No ☐ Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Plasma for PK ☐ PBMC for PK ■ Rectal swabs for lab ☐
Was specimen collected?	Yes ☐ No ☐ Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Plasma for PK ☐ PBMC for PK ☐ Rectal swabs for lab ■
Was specimen collected?	Yes ☐ No ☐ Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐ Not stored ☐

Form: PK Specimen Collection and Storage

If "Not stored", record reason why sample was not stored (max. 200 characters).	

Form: Product Dispensation and Returns

Was study product provided to the participant?	Yes ☐ No ☐
If product was provided outside of the protocol specified schedule, what was the reason?	Lost ☐ Ran out ☐ Spilled ☐ Damaged ☐ Other ☐
If "Other", specify.	_____
Date product provided	_____
Number of tablets provided	_____
Number of TFV douches provided	_____
Was study product returned by the participant?	Yes ☐ No ☐
Date study product returned	_____
Number of unused tablets returned	_____
Number of unused TFV douches returned	_____
Number of opened TFV douches returned	_____
Comments (max. 200 characters):	_____

Form: Product Reconciliation

Total number of tablets taken based on product return	
Total number of tablets taken based on daily eDiaries	
Total number of sachets taken based on product return	
Total number of sachets taken based on daily eDiaries	
Complete the below section if there is a discrepancy.	
Convergence comments (max. 500 characters):	
Most likely number of doses taken based on Data Convergence Interview	
Developer field	

Form: Protocol Devaitions Log Line #_____

Site awareness date	_____
Deviation start date	_____
Deviation stop date	_____
Has or will this deviation be reported to local IRB/EC?	Yes ☐ No ☐
Is this deviation related to a local, national, regional, or global disruptive event (e.g., COVID-19 pandemic, natural disaster, geopolitical conflict)?	Yes ☐ No ☐
Deviation category	Informed assent/consent process deviation ☐ Did not meet eligibility criteria ☐ Failure to follow trial randomization or blinding procedures ☐ Conduct of non-protocol procedure ☐ Visit completed outside of window ☐ Blood volume maximum exceeded ☐ Study product management deviation ☐ Study product dispensing error ☐ Study product administration error ☐ AE/SAE/EAE reporting deviation ☐ Physical assessment deviation ☐ Lab assessment deviation ☐ Specimen handling deviation ☐ Behavioral intervention deviation ☐ Breach of confidentiality ☐ Staff performing duties that they are not qualified or delegated to perform ☐ Use of non-IRB/EC-approved materials ☐ IRB, ethics, or regulatory review deviation ☐ Other ☐
Provide a description of the deviation	_____

Form: Social Impact

Log Line #_____

Date reported to site	
Concisely describe social impact (max. 200 characters).	
Onset date	
Reported at visit code	V1.0 - Screening ☐ V2.0 - Enrollment - Start Period 1 ☐ V201.0 - Period 1 - Day 1 ☐ V202.0 - Period 1 - Day 2 ☐ V203.0 - Period 1 - Day 4 ☐ V204.0 - Period 1 - Day 8 ☐ V3.0 - Mid Period 1 ☐ V4.0 - End Period 1 ☐ V5.0 - Start Period 2 ☐ V501.0 - Period 2 - Day 1 ☐ V502.0 - Period 2 - Day 2 ☐ V503.0 - Period 2 - Day 4 ☐ V504.0 - Period 2 - Day 8 ☐ V6.0 - Mid Period 2 ☐ V7.0 - End Period 2 ☐ V8.0 - Health Contact ☐ Interim visit ☐
If "Interim visit", specify interim visit code.	
Social impact	Personal Relationships - Had any negative experiences with family, friends, significant others, or sex partners. ☐ Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization. ☐ Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work. ☐ Education - Been turned down by an educational program, told to leave an educational program, sudy visits interfering with school attendance/performance, or experienced other problems at school. ☐

Form: Social Impact Log Line #_____

	Medical/Dental - Been told you need to have an HIV test by a health care provider, been refused medical or dental treatment or treated negatively by a health care provider. ☐
	Health Insurance/Medical Aid/Hospital Plan - Lost your health insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy. ☐
	Life Insurance/Funeral Coverage - Lost your life insurance policy or funeral cover policy, had a problem getting new life insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy. ☐
	Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing. ☐
	Military/Other Government Agency - Had a problem with the military or any other government agencies. ☐
	Other - Had other problems not covered in the list above. ☐
If "Other", specify (max. 200 characters):	_____
What impact has this situation had on the participant's quality of life?	No disturbance ☐
	Minimal disturbance ☐
	Moderate disturbance, no significant impact ☐
	Major disturbance with significant impact ☐
Describe what was done by staff and participant to address social impact (max. 200 characters).	
Participant	_____
Staff	_____
Record current status.	Unresolved ☐
	Unresolved at end of study ☐
	Unable to resolve no further action taken ☐
	Resolved ☐
If social impact status is "Unable to resolve no further action taken" or "Resolved", record closure date.	_____
Adverse event, if applicable	_____

Form: Specimen Collection and Storage

Specimen type	Plasma ■
	Dried blood spots ☐
	Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐
	Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Plasma ☐
	Dried blood spots ■
	Rectal swabs ☐
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐
	Not stored ☐
If "Not stored", record reason why sample was not stored (max. 200 characters).	
Specimen type	Plasma ☐
	Dried blood spots ☐
	Rectal swabs ■
Was specimen collected?	Yes ☐
	No ☐
	Not required at this visit ☐
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	
Specimen collection time	
Was sample stored?	Stored ☐
	Not stored ☐

Form: Specimen Collection and Storage

If "Not stored", record reason why sample was not stored (max. 200 characters).	

Form: STI Test Results

Specimen collection date _____

SYPHILIS TESTING

Select "Not done" for any individual test that was not done.

Syphilis Testing not done/ not collected ☐

Go to "N.Gonnorrhea and C. Trachomatis Testing".

Algorithm used
- Traditional ☐
- Reverse ☐

Treponemal
- Not done ☐
- Not detected/Negative ☐
- Positive/Reactive ☐
- Invalid ☐
- Indeterminate ☐

Non-Treponemal
- Not done ☐
- Not detected/Negative ☐
- Positive/Reactive ☐
- Invalid ☐
- Indeterminate ☐

Syphilis titer if indicated _____

Or ☐

N/A

Second Treponemal test
- Not done ☐
- Not detected/Negative ☐
- Positive/Reactive ☐
- Invalid ☐
- Indeterminate ☐

N. GONORRHEA AND C. TRACHOMATIS TESTING

Select "Not done" for any individual test that was not done.

N. gonorrhea – urine
- Not done ☐
- Not detected/Negative ☐
- Positive/Reactive ☐
- Invalid ☐
- Indeterminate ☐

C. trachomatis –urine
- Not done ☐
- Not detected/Negative ☐
- Positive/Reactive ☐

Form: STI Test Results

	Invalid ☐
	Indeterminate ☐
N. gonorrhea – rectal swab	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐
C. trachomatis - rectal swab	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐
N. gonorrhea – oropharyngeal swab	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐
C. trachomatis - oropharyngeal swab	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐

HSV-2 TESTING

Select "Not done" for any individual test that was not done.

HSV-2 - rectal swab	Not done ☐
	Not detected/Negative ☐
	Positive/Reactive ☐
	Invalid ☐
	Indeterminate ☐

If any tests were "Positive/Reactive", action(s) taken:

Mark "None" or all that apply.

None	☐
Medication(s)	☐
Therapeutic procedure/surgery	☐
Diagnostic procedure	☐
Referral	☐

Other	☐
If "Other", specify (max. 200 characters):	_____
Mark if a new STI/GTI Test Results eCRF is required to complete specimen collection requirements for this visit.	☐
Comments (max. 200 characters):	_____

Form: Study Termination

Date of study exit	
Primary reason for completion/discontinuation	Scheduled exit visit/end of study ☐ Death ☐ Participant is unwilling or unable to comply with required study procedures ☐ Lost to follow-up ☐ Investigator decision ☐ Early study closure ☐ Protocol deviation ☐ Adverse event ☐ Withdrawal of consent by participant ☐ Study terminated by sponsor ☐ HIV infection ☐ Other ☐
If "Other", specify (max. 200 characters):	
If "Death", enter date of death.	
If "Adverse event" or "Death", select applicable adverse event.	

Form: Vital Signs

Were vital signs done?	Yes ☐ No ☐
Date of assessment	
Height	Fixed Unit: cm
Weight	Fixed Unit: kg
Body temperature	Fixed Unit: C
Systolic blood pressure	Fixed Unit: mmHg
Diastolic blood pressure	Fixed Unit: mmHg
Pulse	Fixed Unit: beats/min

Form: Daily eDiary Tab

Date of eDiary entry	
Did you have receptive anal sex between 12 noon yesterday and 12 noon today?	Yes ☐ No ☐
How many PrEP tablets did you take within 2 to 24 hours before having receptive anal sex?	
You entered a number greater than what you were instructed to use. If this was an error, please return to that question and correct the response. If this was not an error, please enter the reason you took the additional pill(s). (max. 450 characters):	
Did you douche (with tap or bottled water) at least 1 hour prior to having receptive anal sex?	Yes ☐ No ☐
How many PrEP tablets did you take between 12 noon yesterday and 12 noon today?	
You entered a number greater than what you were instructed to use. If this was an error, please return to that question and correct the response. If this was not an error, please enter the reason you took the additional pill(s). (max. 450 characters):	
Did you douche (with tap or bottled water) 0-24 hours after taking the 2-pill dose?	Yes ☐ No ☐

Form: Daily eDiary Douche

Date of eDiary entry	
Did you have receptive anal sex between 12 noon yesterday and 12 noon today?	Yes ☐ No ☐
How many TFV douches, prepared with the packet, did you use within 1 to 24 hours before having receptive anal sex? (Please count each one separately)	
You entered a number greater than what you were instructed to use. If this was an error, please return to that question and correct the response. If this was not an error, please enter the reason you applied the additional douche(s). (max. 450 characters):	
How many plain water douches with a bulb or bottle did you use in between your TFV douches?	0 ☐ 1 or 2 ☐ 3 or 4 ☐ 5 or more ☐ I used a hose to douche ☐
How many TFV douches, prepared with the packet, did you use between 12 noon yesterday and 12 noon today? (Please count each one separately)	
You entered a number greater than what you were instructed to use. If this was an error, please return to that question and correct the response. If this was not an error, please enter the reason you applied the additional douche(s). (max. 450 characters):	