CRF TITLE	ACRONYM	PLATE #	VERSION 1 10-Jun-2022	SET 2 08-Dec-2022
Visit Summary	VS	001	10-Jun-2022	V1, 10-Jun-2022
Demographics	DEM	010	10-Jun-2022	V2, 08-Dec-2022
Eligibility	ELIG	015	10-Jun-2022	V1, 10-Jun-2022
Enrollment	ENR	025	10-Jun-2022	V1, 10-Jun-2022
PrEP Acceptance, Enrollment	PACC	030	10-Jun-2022	V1, 10-Jun-2022
PrEP Dispensation	PDISP	035	10-Jun-2022	V1, 10-Jun-2022
Specimen Storage	SPS	038	10-Jun-2022	V2, 08-Dec-2022
Baseline Reproductive History	BRH	040	10-Jun-2022	V1, 10-Jun-2022
Contraceptive Use	CU	045	10-Jun-2022	V2, 08-Dec-2022
Baseline Health Status, page 1	BHS-1	051	10-Jun-2022	V2, 08-Dec-2022
Baseline Health Status, page 2	BHS-2	052	10-Jun-2022	V2, 08-Dec-2022
Follow-up Health Status, page 1	FHS-1	055	10-Jun-2022	V2, 08-Dec-2022
Follow-up Health Status, page 2	FHS-1	056	10-Jun-2022	V2, 08-Dec-2022
PrEP Acceptance Follow-up, page 1	FPACC-1	061	10-Jun-2022	V1, 10-Jun-2022
PrEP Acceptance Follow-up, page 2	FPACC-2	062	10-Jun-2022	V1, 10-Jun-2022
PrEP Acceptance Follow-up, page 3	FPACC-3	063	10-Jun-2022	V2, 08-Dec-2022
PrEP Acceptance Follow-up (M6), page 1	FPACC-1	061	10-Jun-2022	V1, 10-Jun-2022
PrEP Acceptance Follow-up (M6), page 2	FPACC-2	062	10-Jun-2022	V1, 10-Jun-2022
PrEP Acceptance Follow-up (M6), page 3	FPACC-3	063	10-Jun-2022	V2, 08-Dec-2022
PrEP Decision Support Tool, page 1	DST-1	065	10-Jun-2022	V1, 10-Jun-2022
PrEP Decision Support Tool, page 2	DST-2	066	10-Jun-2022	V1, 10-Jun-2022
Lab Results (Screening)	LAB	075	10-Jun-2022	V1, 10-Jun-2022
Lab Results (Enrollment)	LAB	075	10-Jun-2022	V1, 10-Jun-2022
Lab Results	LAB	075	10-Jun-2022	V1, 10-Jun-2022
Screening HIV Positive	POS	085	10-Jun-2022	V2, 08-Dec-2022
Follow-up HIV Positive/Possible Seroconversion	FPOS	087	10-Jun-2022	V2, 08-Dec-2022
Behavior Assessment (Sexual), page 1	BAS-1	101	10-Jun-2022	V1, 10-Jun-2022
Behavior Assessment (Sexual), page 2	BAS-2	102	10-Jun-2022	V1, 10-Jun-2022
Behavior Assessment (Sexual), page 3	BAS-3	103	10-Jun-2022	V1, 10-Jun-2022
Relationship Dynamics	RD	105	10-Jun-2022	V1, 10-Jun-2022
Feelings and Worries	FW	107	10-Jun-2022	V1, 10-Jun-2022
Mental Health Screening	MHS	109	10-Jun-2022	V1, 10-Jun-2022
Substance Use, page 1	SU-1	111	10-Jun-2022	V1, 10-Jun-2022
Substance Use, page 2	SU-2	112	10-Jun-2022	V1, 10-Jun-2022
Intimate Partner Violence	IPV	115		V1, 08-Dec-2022
STI Assessment	STIA	120	10-Jun-2022	V2, 08-Dec-2022
PrEP Discontinuation	PDISC	135	10-Jun-2022	V1, 10-Jun-2022
HLA Consent and Specimen Collection	HLA	138		V1, 08-Dec-2022
New Protocol Consent Log	NPC	250	10-Jun-2022	V1, 10-Jun-2022
Pregnancy Report	PREG	330	10-Jun-2022	V2, 08-Dec-2022
Pregnancy Outcome	P-OUT	342	10-Jun-2022	V2, 08-Dec-2022
Protocol Variance	DV	450	10-Jun-2022	V1, 10-Jun-2022
Participant Transfer	TRAN	465	10-Jun-2022	V1, 10-Jun-2022
Participant Receipt	REC	466	10-Jun-2022	V1, 10-Jun-2022
Social Harms	SH	480	10-Jun-2022	V2, 08-Dec-2022
Termination	TERM	490	10-Jun-2022	V1, 10-Jun-2022

CRF 140/001 (VS)

INSIGHT

PTID: nn-nn-nnnn-n

Visit:

☐ Delete CRF; reason:

Visit Summary

1. Type of visit:
   - ◯ Follow-up *(M1, M3, M6)*
   - ☐ End of study
   - ◯ Interim
   - ◯ Missed → ***Go to item 5.***

2. Visit date: DD/MMM/YYYY

3. Location of study visit:
   - ◯ Clinic
   - ◯ Participant home
   - ◯ Phone visit
   - ◯ Other, specify:

4. Reason for interim visit: *Check all that apply.*
   - ☐ Report side effects
   - ☐ Complete scheduled procedures
   - ☐ PrEP related
   - ☐ HIV testing
   - ☐ STI symptoms or treatment
   - ☐ Suspected or confirmed pregnancy
   - ☐ Other, specify:

5. Reason for missed visit: *Check all that apply.*
   - ☐ Traveling or out of the area
   - ☐ Refused visit
   - ☐ Participant withdrew from study: ***Complete TERM***.
   - ☐ Work or school issues
   - ☐ Family or personal issues
   - ☐ Planned absence
   - ☐ Transportation issues
   - ☐ Illness or hospitalized
   - ☐ Incarcerated
   - ☐ Relocated or moved
   - ☐ Unable to schedule appointment within allowable window
   - ☐ Unable to contact
   - ☐ Participant deceased: ***Complete TERM.***
   - ☐ Other, specify:

SDV ☐ SDV Date:

CRF 140/010 (DEM) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ Delete CRF; reason:

Demographics

1. Date of birth: DD/MMM/YYYY ***OR*** **Age in years:** nn

2. Current relationship status:
   - ◯ Single/not partnered
   - ◯ Partnered/not married
   - ◯ Married (polygamous)
   - ◯ Married (monogamous)

3. With whom does the participant live? *(mark all that apply)*
   - ☐ Parents
   - ☐ Other family
   - ☐ Partner/husband
   - ☐ Friends
   - ☐ Lives alone
   - ☐ Other, specify:

4. Highest level of education:
   - ◯ No schooling
   - ◯ Primary school, not complete
   - ◯ Primary school, complete
   - ◯ Secondary school, not complete
   - ◯ Secondary school, complete
   - ◯ Attended post-secondary school

5. Does the participant own a mobile phone? ◯ Yes ◯ No → ***If no, go to item 6.***

   5a. Is this mobile phone a smartphone? ◯ Yes ◯ No

6. What is the participant's preferred language?

7. Does the participant's partner/ husband provide her with financial and/or material support? ◯ Yes ◯ No ◯ N/A, no partner

8. Does the participant earn an income of her own? ◯ Yes ◯ No

9. What is the participant's primary job/ occupation?
   - ◯ Unemployed/no job
   - ◯ Student
   - ◯ Parent caring for own child/ housewife
   - ◯ Household help/child care for others
   - ◯ Employment with a steady salary/ formal sector (e.g., teaching, office work)
   - ◯ Employment without a steady salary/ informal sector (e.g. trader, selling goods)
   - ◯ Other, specify:

10. Was this participant enrolled in IMPOWER 22 at this site? ◯ Yes ◯ No

CRF 140/015 (ELIG) | PTID: nn-nn-nnnn-n | Visit: | Visit date: DD/MMM/YYYY

INSIGHT

☐ Delete CRF; reason:

Eligibility

1. Is the participant 18-30 years old (or 16-30 years old where permissible by national and local ethics approval)? ◯ Yes ◯ No

2. Is the participant willing to provide independent, written, informed consent or assent for the study? ◯ Yes ◯ No → ***If no, end of form.***

   2a. Date informed consent or assent for the study was marked or signed: DD/MMM/YYYY

3. If the participant is <18 years old and regulations require guardian consent, is the guardian willing to provide independent, written, informed consent for the study? ◯ Yes ◯ No ◯ N/A
   If no, end of form.
   If N/A, go to item 4.

   3a. Date informed consent for the study was marked or signed: DD/MMM/YYYY

4. Is the participant born female? ◯ Yes ◯ No

5. Is the participant willing and able to provide adequate locator information? ◯ Yes ◯ No

6. Is the participant sexually active (has had vaginal sex within the last 3 months)? ◯ Yes ◯ No

7. Is the participant HIV negative based on HIV rapid tests? ◯ Yes ◯ No

8. Is the participant interested in the use of PrEP for HIV prevention?

   Strongly Agree ◯ | *Agree* ◯ | *Neutral* ◯ | *Disagree* ◯ | *Strongly Disagree* ◯

   Participant is ineligible for enrollment.

9. Does the participant meet all eligibility criteria? ◯ Yes ◯ No

CRF 140/025 (ENR)

INSIGHT

PTID: nn-nn-nnnn-n

Visit:

Visit date: DD/MMM/YYYY

☐ Delete CRF; reason:

Enrollment

1. Is the participant enrolling in the study? ◯ Yes ◯ No → ***If no, go to item 1b.***

1a. Date of enrollment: DD/MMM/YYYY

1b. If no, reason(s) for not enrolling: *(select all that apply)*

- ☐ Participant tested HIV positive
- ☐ Participant declined
- ☐ Other, specify:

SDV ☐ SDV Date:

CRF 140/030 (PACC) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Acceptance, Enrollment

PrEP Acceptance

1. Is the participant willing to start PrEP today? ◯ Yes → ***Go to item 1c.*** ◯ No → ***Go to item 1d.*** ◯ Currently taking PrEP

1a. If currently taking PrEP, when did participant start taking it? DD/MMM/YYYY

1b. Has the participant told anyone that they are taking PrEP? ◯ Yes → ***Go to item 1ci.*** ◯ No → ***If no, end of form.***

1c. Is the participant planning on telling anyone they are starting PrEP? ◯ Yes ◯ No → ***If no, end of form.***

1ci. If yes, who? *(mark all that apply)*

- ☐ Mother
- ☐ Sister
- ☐ Aunt
- ☐ Father
- ☐ Other family, specify:
- ☐ Primary sexual partner
- ☐ A sexual partner other than primary
- ☐ Close friend
- ☐ Acquaintance
- ☐ Other, specify:

1d. If no, what are the reasons the participant is not interested in starting PrEP? *(mark all that apply)*

- ☐ Size/taste of pills
- ☐ Burdensome to take the tablet every day
- ☐ People should not take drugs unless they are sick
- ☐ Had or concerned about side effects
- ☐ People might think I have HIV
- ☐ My partner will be upset
- ☐ Friend(s) discouraged it
- ☐ Partner(s) discouraged it
- ☐ Family discouraged it
- ☐ I do not think I am at risk of HIV
- ☐ I am doing other things to protect against HIV
- ☐ I do not have a place to store it
- ☐ Believe it may affect my fertility
- ☐ Other, specify:

1di. Of these reasons, which is the **main** reason the participant is not interested in starting PrEP? *(choose only one)*

- ◯ Size/taste of pills
- ◯ Burdensome to take the tablet every day
- ◯ People should not take drugs unless they are sick
- ◯ Had or concerned about side effects
- ◯ People might think I have HIV
- ◯ My partner will be upset
- ◯ Friend(s) discouraged it
- ◯ Partner(s) discouraged it
- ◯ Family discouraged it
- ◯ I do not think I am at risk of HIV
- ◯ I am doing other things to protect against HIV
- ◯ I do not have a place to store it
- ◯ Believe it may affect my fertility
- ◯ Other, specify:

CRF 140/035 (PDISP) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Dispensation

PrEP Dispensation

1. If participant is accepting PrEP today:

   1a. Record number of bottles given: nn

2. Was the participant counseled about adherence and PrEP use? ◯ Yes ◯ No

Comments:

CRF 140/038 (SPS) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Specimen Storage

Specimen storage

1. Was DBS sample collected for TFV-DP level testing? ◯ Yes ◯ No ◯ Not required

If no or not required, end of form.

1a. Sample ID:

1b. Number of spots: n

HPV swab

2. Was swab collected for HPV testing? *(Applicable at M6 or possible seroconversion visit)* ◯ Yes ◯ No ◯ Not required

If no or not required, end of form.

2a. Sample ID:

Comments:

CRF 140/040 (BRH) PTID: Visit: Visit date:

INSIGHT

nn-nn-nnnn-n | | DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Baseline Reproductive History

1. Date of first day of last menstrual period: DD/MMM/YYYY ***OR*** ☐ Unknown ☐ N/A (no menses in past 6 months)

2. How many times has the participant ever been pregnant? nn → ***If 0, go to item 4.***

   2a. Date last pregnancy ended: DD/MMM/YYYY ***OR*** ☐ Unknown ☐ Currently pregnant

3. How many living children does the participant have? nn → ***If 0, go to item 4.***

   3a. Age of last born child: nn *years old*

4. Does the participant want to have any/additional children in the future? ◯ Yes ◯ No ◯ Maybe

5. Is the participant currently trying to conceive? ◯ Yes ◯ No

CRF 140/045 (CU)

INSIGHT

PTID: nn-nn-nnnn-n

Visit:

Visit date: DD/MMM/YYYY

☐ CRF not administered

☐ Delete CRF; reason:

Contraceptive Use

1. Which contraceptive method(s) is the participant currently using? *(mark all that apply)*

- ☐ Not currently using a contraceptive method
- ☐ IUD
- ☐ Implant
- ☐ DMPA
- ☐ NET-En
- ☐ Oral contraceptives
- ☐ Patch
- ☐ DMPA-SC
- ☐ Emergency Contraception
- ☐ Intravaginal ring (e.g., NuvaRing)
- ☐ Male/female condoms
- ☐ Diaphragm/sponge
- ☐ Other barrier method
- ☐ Spermicide alone
- ☐ Natural methods, such as withdrawal or rhythm method
- ☐ Tubal ligation, hysterectomy, or other surgical sterilization
- ☐ Other, specify:

2. How satisfied are you with your current contraceptive method?

◯ Very satisfied ◯ Somewhat satisfied ◯ Neutral ◯ Somewhat dissatisfied ◯ Totally dissatisfied

2a. If somewhat or totally dissatisfied, why are you dissatisfied? *(mark all that apply)*

- ☐ Frequency of bleeding
- ☐ Volume of bleeding
- ☐ Weight change
- ☐ Availability of method at clinic
- ☐ Other, specify:

3. Is the participant continuing this method today? ◯ Yes ◯ No

→ ***If yes, end of form.***

3a. If no, why is the participant not continuing this method? *(mark all that apply)*

- ☐ Does not like the frequency of use
- ☐ Does not like the side effects
- ☐ Does not like the product form
- ☐ Wants more effective method
- ☐ Other, specify:

3.a.i. What method did the participant receive today? *(mark all that apply)*

- ☐ No method
- ☐ IUD
- ☐ Implant
- ☐ DMPA
- ☐ NET-En
- ☐ Oral contraceptives
- ☐ Patch
- ☐ DMPA-SC
- ☐ Emergency Contraception
- ☐ Intravaginal ring
- ☐ Male/female condoms
- ☐ Diaphragm/sponge
- ☐ Other barrier method
- ☐ Spermicide alone
- ☐ Natural methods, such as withdrawal or rhythm method
- ☐ Tubal ligation, hysterectomy, or other surgical sterilization
- ☐ Other, specify:

4. Have you ever stopped contraception due to side effects? *(applicable at M6 only)* ◯ Yes ◯ No ◯ Don't know

→ ***If no, or don't know, End of form.***

4a. If yes, did you stop contraception due to changes in menstrual bleeding pattern? ◯ Yes ◯ No

SDV ☐ SDV Date:

CRF 140/051 (BHS-1) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Baseline Health Status, page 1

Vital Signs

1. Height ☐ Not done nnn *cm*
2. Weight ☐ Not done nnn *kg*
3. Blood pressure ☐ Not done nnn / nnn *mm/Hg*
   systolic *diastolic*
4. Temperature ☐ Not done nn.n *°C*

PrEP/PEP use

5. Has the participant ever used post-exposure prophylaxis (PEP) for HIV? ◯ Yes ◯ No
6. Has the participant ever used PrEP for HIV prevention? ◯ Yes ◯ No → ***If no, go to item 8.***
   6a. Month and year of last PrEP use: MMM/YYYY
7. Is the participant currently using PrEP? ◯ Yes ◯ No

HIV Testing History

8. Before today has the participant ever tested for HIV? ◯ Yes ◯ No → ***If no, go to item 9.***
   8a. When was participant's last HIV test? ◯ More than six months ◯ Within the last six months ◯ Don't know
   8b. What were the results of the HIV test? ◯ Negative ◯ Positive ◯ Didn't receive the results

Baseline health status

9. Date of the first day of the last menstrual period: DD/MMM/YYYY
10. Is the participant currently known to be pregnant? ◯ Yes ◯ No
11. Is the participant currently breastfeeding? ◯ Yes ◯ No
12. Has the participant received at least one dose of a HPV vaccine? ◯ Yes ◯ No
13. Has the participant been treated for vaginal symptoms (e.g., discharge) or possible STI within the past 6 months? ◯ Yes ◯ No

(Continue to BHS-2)

CRF 140/052 (BHS-2) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Baseline Health Status, page 2

14. Has the participant had any of the following symptoms in the last week?

14a. Runny nose	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14b. Sneezing	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14c. Sore throat	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14d. Dry cough	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14e. Fatigue	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14f. Chills	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14g. Nausea	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14h. Diarrhea	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14i. Abdominal pain	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14j. Nasal congestion	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14k. Loss of sense of smell	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14l. Fever	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14m. Shortness of breath	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14n. Muscle aches	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14o. Headache	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14p. Vomiting	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14q. Rash	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
14r. Other, specify:	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No

15. Is the participant currently having any signs or symptoms of COVID? ◯ Yes ◯ No

16. Has the participant ever had known or suspected COVID? ◯ Yes ◯ No

17. Has the participant received at least one dose of a COVID vaccine? ◯ Yes ◯ No

18. Is the participant currently having any signs or symptoms of acute HIV? ◯ Yes ◯ No

Do not dispense PrEP. Schedule participant for repeat testing in 2-4 weeks.

19. Was the DCE conducted today? ◯ Yes ◯ No

20. Comments:

CRF 140/055 (FHS-1) PTID: Visit: Visit date:

INSIGHT

nn-nn-nnnn-n | | DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Follow-up Health Status, page 1

Vital Signs

1. Weight ☐ Not done nnn *kg*

2. Blood pressure ☐ Not done nnn / nnn *mm/Hg*
   systolic *diastolic*

3. Temperature ☐ Not done nn.n *°C*

Health status

4. Date of the first day of the last menstrual period: DD/MMM/YYYY

5. Is the participant currently known to be pregnant? ◯ Yes ◯ No
   **If clinically indicated, perform pregnancy test*
   If yes, go to item 6.

   5a. Is the participant currently trying to conceive? ◯ Yes ◯ No

6. Is the participant currently breastfeeding? ◯ Yes ◯ No

7. Has the participant had any of the following symptoms in the last week?

7a. Runny nose	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7b. Sneezing	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7c. Sore throat	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7d. Dry cough	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7e. Fatigue	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7f. Chills	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7g. Nausea	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7h. Diarrhea	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7i. Abdominal pain	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7j. Nasal congestion	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7k. Loss of sense of smell	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7l. Fever	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7m. Shortness of breath	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No

CRF 140/056 (FHS-2) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Follow-up Health Status, page 2

7. Has the participant had any of the following symptoms in the last week?

7n. Muscle aches	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7o. Headache	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7p. Vomiting	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7q. Rash	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No
7r. Other, specify:	◯ Yes	◯ No	If yes, current/ongoing?	◯ Yes	◯ No

8. Is the participant currently having any signs or symptoms of COVID? ◯ Yes ◯ No

9. Has the participant had known or suspected COVID since the last visit? ◯ Yes ◯ No

10. Has the participant received at least one dose of a COVID vaccine since the last visit? ◯ Yes ◯ No

11. Is the participant currently having any signs or symptoms of acute HIV? ◯ Yes ◯ No
→ ***Do not dispense PrEP. Schedule participant for repeat testing in 2-4 weeks.***

12. Was the DCE conducted today? *(M1 and M3 only)* ◯ Yes ◯ No

13. Since the last visit, has the participant experienced verbal, physical, economic, or other abuse? ◯ Yes ◯ No
→ ***If yes, complete a Social Harms CRF.***

14. Since the last visit, has the participant been verbally, physically, or economically abused or experienced negative social impacts as a result of participation in this study? ◯ Yes ◯ No
→ ***If yes, complete a Social Harms CRF.***

15. Have you ever had treatment for abnormalities of the cervix (mouth of the womb) to prevent cervical cancer? *(applicable at M6 only)* ◯ Yes ◯ No ◯ Don't know

16. Comments:

CRF 140/061 (FPACC-1) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Acceptance Follow-up, page 1

1. Did participant receive PrEP at last visit? ◯ Yes ◯ No → ***If no, go to item 5.***

These are interviewer-administered questions and should be read aloud directly as written.

1a. How well do you think you have taken your PrEP, as directed, in the past 30 days?

◯ Very poor ◯ Poor ◯ Fair ◯ Good ◯ Very good ◯ Excellent

1b. In the past 30 days, do you think you took PrEP well enough to be protected from HIV? ◯ Yes ◯ No ◯ Don't know

1c. Have you had any side effects related to PrEP since the last visit? ◯ Yes ◯ No → ***If no, go to item 1d.***

1.c.i. Did you consider the side effects to be: ◯ Mild ◯ Moderate ◯ Severe

1.c.ii. Were you worried about the side effects? ◯ Yes ◯ No

1d. Have you told anyone that you are using PrEP? ◯ Yes ◯ No → ***If no, go to item 1e.***

1.d.i. If yes, who?	1.d.ii. If told, was their reaction supportive?
☐ Mother	◯ Yes ◯ No
☐ Sister	◯ Yes ◯ No
☐ Aunt	◯ Yes ◯ No
☐ Father	◯ Yes ◯ No
☐ Other family, specify:	◯ Yes ◯ No
☐ Primary sexual partner	◯ Yes ◯ No
☐ A sexual partner other than primary	◯ Yes ◯ No
☐ Close friend	◯ Yes ◯ No
☐ Acquaintance	◯ Yes ◯ No
☐ Other, specify:	◯ Yes ◯ No

CRF 140/062 (FPACC-2) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Acceptance Follow-up, page 2

1e. Has anyone unintentionally seen your PrEP pills/bottles or found out that you are taking PrEP? ◯ Yes ◯ No → ***If no, go to item 2.***

1.e.i. Did that bother you? ◯ Yes ◯ No

1.e.ii. Did that cause you any problems? ◯ Yes ◯ No → ***If no, go to item 1.e.iii.***

1.e.ii.1. What kind of problems? *(mark all that apply)*

- ☐ Anxiety/worry
- ☐ Physical abuse
- ☐ Embarrassment
- ☐ Emotional abuse
- ☐ Other, specify:

1.e.iii. Did you or someone else get rid of your PrEP pills/ bottles? ◯ Yes ◯ No

2. Taking PrEP can impact people's lives differently. How has taking PrEP impacted your life: *(Mark all that apply)*

- ☐ I feel like I'm protecting myself when I use PrEP
- ☐ I feel freer when I have sex
- ☐ I'm less worried about getting HIV
- ☐ I feel like I'm taking control by taking PrEP
- ☐ I worry that someone will find out I'm taking PrEP
- ☐ I worry that my partner will be upset if he finds out I'm taking PrEP
- ☐ I worry that people will judge me or think I'm promiscuous if they find out I'm taking PrEP
- ☐ I worry that I will have to take PrEP forever
- ☐ I worry that I will forget to take my PrEP
- ☐ I worry that I will have trouble getting to the clinic to pick up my PrEP
- ☐ I worry about what PrEP is doing to my body
- ☐ I worry PrEP will impact my fertility
- ☐ None of these ways

3. Sometimes people have trouble taking their PrEP. Have you experienced any of the following barriers to taking PrEP? *(Mark all that apply)*

- ☐ Sometimes I forget to take my pills
- ☐ Sometimes I don't have money to get to the clinic
- ☐ I don't have a place to store my PrEP
- ☐ My friend(s) discouraged me from taking PrEP
- ☐ My partner(s) discouraged me from taking PrEP
- ☐ My family discouraged me from taking PrEP
- ☐ I don't like the way PrEP makes me feel
- ☐ I don't think I am at risk of getting HIV
- ☐ I prefer to use other methods of HIV prevention
- ☐ I forget to take my pills with me when I travel
- ☐ It's hard to get away from school or work to pick up my pills
- ☐ Other, specify:
- ☐ I don't have any barriers to taking PrEP

End of interviewer-administered questions.

PrEP Acceptance Follow-up, page 3

4. Did participant receive counseling on their urine drug level results today? ◯ Yes ◯ No ◯ Testing not done

If no or not done, go to item 5.

Item 4a is an interviewer-administered question and should be read aloud directly as written.

4a. How did you find the counseling about whether you had tenofovir in your urine? *(Mark all that apply)*

- ☐ The positive urine result motivates me to keep taking PrEP
- ☐ The negative result helps me think about ways to avoid missing my PrEP doses
- ☐ The negative result surprised me
- ☐ The negative result did not surprise me
- ☐ The counselor helped me think about reasons for missing doses and ways to remember to take my PrEP
- ☐ Other, specify:

End of interviewer-administered questions.

5. Did participant accept PrEP today? ◯ Yes ◯ No

If yes, go to item 6, submit PrEP Dispensation CRF.

5a. If no, what is the **main** reason the participant did not accept PrEP? *(choose only one)*

- ◯ Size/taste of pills
- ◯ Burdensome to take the tablet every day
- ◯ People should not take drugs unless they are sick
- ◯ Had or concerned about side effects
- ◯ People might think I have HIV
- ◯ My partner will be upset
- ◯ Friend(s) discouraged it
- ◯ Partner(s) discouraged it
- ◯ Family discouraged it
- ◯ I do not think I am at risk of HIV
- ◯ I am doing other things to protect against HIV
- ◯ I do not have a place to store it
- ◯ Believe it may affect my fertility
- ◯ Other, specify:

CRF 140/061 (FPACC-1) PTID: Visit: Visit date:

INSIGHT

nn-nn-nnnn-n

DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Acceptance Follow-up (M6), page 1

1. Did participant receive PrEP at last visit? ◯ Yes ◯ No → ***If no, go to item 5.***

These are interviewer-administered questions and should be read aloud directly as written.

1a. How well do you think you have taken your PrEP, as directed, in the past 30 days?

◯ Very poor ◯ Poor ◯ Fair ◯ Good ◯ Very good ◯ Excellent

1b. In the past 30 days, do you think you took PrEP well enough to be protected from HIV? ◯ Yes ◯ No ◯ Don't know

1c. Have you had any side effects related to PrEP since the last visit? ◯ Yes ◯ No → ***If no, go to item 1d.***

1.c.i. Did you consider the side effects to be: ◯ Mild ◯ Moderate ◯ Severe

1.c.ii. Were you worried about the side effects? ◯ Yes ◯ No

1d. Have you told anyone that you are using PrEP? ◯ Yes ◯ No → ***If no, go to item 1e.***

1.d.i. If yes, who?	1.d.ii. If told, was their reaction supportive?
☐ Mother	◯ Yes ◯ No
☐ Sister	◯ Yes ◯ No
☐ Aunt	◯ Yes ◯ No
☐ Father	◯ Yes ◯ No
☐ Other family, specify:	◯ Yes ◯ No
☐ Primary sexual partner	◯ Yes ◯ No
☐ A sexual partner other than primary	◯ Yes ◯ No
☐ Close friend	◯ Yes ◯ No
☐ Acquaintance	◯ Yes ◯ No
☐ Other, specify:	◯ Yes ◯ No

PrEP Acceptance Follow-up (M6), page 2

1e. Has anyone unintentionally seen your PrEP pills/bottles or found out that you are taking PrEP? ◯ Yes ◯ No → ***If no, go to item 2.***

1.e.i. Did that bother you? ◯ Yes ◯ No

1.e.ii. Did that cause you any problems? ◯ Yes ◯ No → ***If no, go to item 1.e.iii.***

1.e.ii.1. What kind of problems? *(mark all that apply)*

- ☐ Anxiety/worry
- ☐ Emotional abuse
- ☐ Physical abuse
- ☐ Other, specify:
- ☐ Embarrassment

1.e.iii. Did you or someone else get rid of your PrEP pills/ bottles? ◯ Yes ◯ No

2. Taking PrEP can impact people's lives differently. How has taking PrEP impacted your life: *(Mark all that apply)*

- ☐ I feel like I'm protecting myself when I use PrEP
- ☐ I worry that people will judge me or think I'm promiscuous if they find out I'm taking PrEP
- ☐ I feel freer when I have sex
- ☐ I worry that I will have to take PrEP forever
- ☐ I'm less worried about getting HIV
- ☐ I worry that I will forget to take my PrEP
- ☐ I feel like I'm taking control by taking PrEP
- ☐ I worry that I will have trouble getting to the clinic to pick up my PrEP
- ☐ I worry that someone will find out I'm taking PrEP
- ☐ I worry about what PrEP is doing to my body
- ☐ I worry that my partner will be upset if he finds out I'm taking PrEP
- ☐ I worry PrEP will impact my fertility
- ☐ None of these ways

3. Sometimes people have trouble taking their PrEP. Have you experienced any of the following barriers to taking PrEP? *(Mark all that apply)*

- ☐ Sometimes I forget to take my pills
- ☐ I don't think I am at risk of getting HIV
- ☐ Sometimes I don't have money to get to the clinic
- ☐ I prefer to use other methods of HIV prevention
- ☐ I don't have a place to store my PrEP
- ☐ I forget to take my pills with me when I travel
- ☐ My friend(s) discouraged me from taking PrEP
- ☐ It's hard to get away from school or work to pick up my pills
- ☐ My partner(s) discouraged me from taking PrEP
- ☐ Other, specify:
- ☐ My family discouraged me from taking PrEP
- ☐ I don't like the way PrEP makes me feel
- ☐ I don't have any barriers to taking PrEP

End of interviewer-administered questions.

CRF 140/063 (FPACC-3) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Acceptance Follow-up (M6), page 3

4. Did participant receive counseling on their urine drug level results today? ◯ Yes ◯ No ◯ Testing not done

If no or not done, go to item 5.

Item 4a is an interviewer-administered question and should be read aloud directly as written.

4a. How did you find the counseling about whether you had tenofovir in your urine? *(Mark all that apply)*

- ☐ The positive urine result motivates me to keep taking PrEP
- ☐ The negative result helps me think about ways to avoid missing my PrEP doses
- ☐ The negative result surprised me
- ☐ The negative result did not surprise me
- ☐ The counselor helped me think about reasons for missing doses and ways to remember to take my PrEP
- ☐ Other, specify:

End of interviewer-administered questions.

5. Did participant accept PrEP today? ◯ Yes ◯ No

If yes, go to item 6, submit PrEP Dispensation CRF.

5a. If no, what is the **main** reason the participant did not accept PrEP? *(choose only one)*

- ◯ Size/taste of pills
- ◯ Burdensome to take the tablet every day
- ◯ People should not take drugs unless they are sick
- ◯ Had or concerned about side effects
- ◯ People might think I have HIV
- ◯ My partner will be upset
- ◯ Friend(s) discouraged it
- ◯ Partner(s) discouraged it
- ◯ Family discouraged it
- ◯ I do not think I am at risk of HIV
- ◯ I am doing other things to protect against HIV
- ◯ I do not have a place to store it
- ◯ Believe it may affect my fertility
- ◯ Other, specify:

6. Did the participant receive a referral for a public PrEP program or HIV prevention/PrEP clinical trial? ◯ Yes ◯ No

If yes, go to item 7.

6a. If no, why did the participant **not** receive a referral? *(Mark all that apply)*

- ☐ Does not want to start or continue taking PrEP
- ☐ Not interested in receiving PrEP from another clinic/study
- ☐ No PrEP programs or studies available for referral
- ☐ Other, specify:

7. In the future, if there are different types of HIV prevention methods available, which type would the participant prefer to use? *(Mark all that apply)*

- ☐ Daily oral PrEP
- ☐ Monthly vaginal ring *(replaced once a month)*
- ☐ Every 2 month injectable
- ☐ Monthly oral PrEP *(one tablet taken once a month)*
- ☐ Weekly oral PrEP *(one tablet taken once a week)*

CRF 140/065 (DST-1) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Decision Support Tool Questionnaire (M6), page 1

These are interviewer-administered questions and should be read aloud directly as written.

	Very Satisfied	*Satisfied*	*Neither satisfied nor dissatisfied*	*Dissatisfied*	*Very Dissatisfied*
1. How satisfied are you with the information you were given today about HIV prevention?	◯	◯	◯	◯	◯

	Strongly agree	*Agree*	*Neither agree nor disagree*	*Disagree*	*Strongly Disagree*
When getting information today about PrEP:					
2. I got all the information I needed.	◯	◯	◯	◯	◯
3. The information was easy to understand.	◯	◯	◯	◯	◯
4. I trusted the information.	◯	◯	◯	◯	◯
5. The information was useful to me.	◯	◯	◯	◯	◯
6. I felt respected.	◯	◯	◯	◯	◯

	A lot <u>more</u> about PrEP	*A little <u>more</u> about PrEP*	*The same amount about PrEP*	*A little <u>less</u> about PrEP*	*A lot <u>less</u> about PrEP*
7. How did using the PrEP decision tool change how much you know about **PrEP overall**, compared to before you used the tool? I now know …	◯	◯	◯	◯	◯
8. How did using the PrEP decision tool change how much you know about **oral PrEP**, compared to before you used the tool? I now know …	◯	◯	◯	◯	◯
9. How did using the PrEP decision tool change how much you know about **vaginal ring PrEP** (e.g., dapivirine ring), compared to before you used the tool? I now know …	◯	◯	◯	◯	◯
10. How did using the PrEP decision tool change how much you know about **injectable PrEP** (e.g., cabotegravir), compared to before you used the tool? I now know …	◯	◯	◯	◯	◯

CRF 140/066 (DST-2) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Decision Support Tool Questionnaire (M6), page 2

	A lot less interested in PrEP	*A little less interested in PrEP*	*No difference*	*A little more interested in PrEP*	*A lot more interested in PrEP*
11. How did using the PrEP decision tool change your interest in **PrEP overall**? It made me...	◯	◯	◯	◯	◯
12. How did using the PrEP decision tool change your interest in using **oral PrEP**? It made me...	◯	◯	◯	◯	◯
13. How did using the PrEP decision tool change your interest in using **vaginal ring PrEP** (e.g., dapivirine ring)? It made me...	◯	◯	◯	◯	◯
14. How did using the PrEP decision tool change your interest in using **injectable PrEP** (e.g., cabotegravir)? It made me...	◯	◯	◯	◯	◯

	I disliked it a lot	*I disliked it a little*	*I liked it a little*	*I liked it a lot*
15. How did you like getting information about PrEP from the tool?	◯	◯	◯	◯

CRF 140/075 (LAB) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Screening Laboratory Results

HIV Test Results

1. HIV rapid test 1 ◯ Positive ◯ Negative ◯ Not done Test kit:
   → ***Complete Screening HIV Positive CRF.***
2. HIV rapid test 2 ◯ Positive ◯ Negative ◯ Not done Test kit:
   → ***Complete Screening HIV Positive CRF.***
3. HIV rapid test 3 ◯ Positive ◯ Negative ◯ Not done Test kit:
   → ***Complete Screening HIV Positive CRF.***

CRF 140/075 (LAB) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Enrollment Laboratory Results

HIV Test Results

1. HIV rapid test 1 ○ Positive ○ Negative ○ Not done Test kit:
   → ***Complete Screening HIV Positive CRF.***

2. HIV rapid test 2 ○ Positive ○ Negative ○ Not done Test kit:
   → ***Complete Screening HIV Positive CRF.***

3. HIV rapid test 3 ○ Positive ○ Negative ○ Not done Test kit:
   → ***Complete Screening HIV Positive CRF.***

Pregnancy/STI Test Results

4. HcG for pregnancy ○ Positive ○ Negative ○ Not done
   → ***If positive, complete PREG CRF.***

5. N. gonorrhoeae ○ Positive ○ Negative ○ Not done

6. C. trachomatis ○ Positive ○ Negative ○ Not done

7. T. vaginalis ○ Positive ○ Negative ○ Not done

8. Syphilis RPR ○ Positive ○ Negative ○ Not done

   8a. Titer result: 1: nn ***OR*** ☐ Not available

9. Syphilis TPPA ○ Positive ○ Negative ○ Not done

Clinical Monitoring for PrEP initiation

10. Creatinine clearance nnn *mL/min* ***OR*** ☐ Not done

11. HBsAg ○ Positive ○ Negative ○ Not done

CRF 140/075 (LAB) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Laboratory Results, Follow-up

HIV Test Results

1. HIV rapid test 1 ○ Positive ○ Negative ○ Not done Test kit:
   → ***Complete Follow-up HIV Positive CRF.***

2. HIV rapid test 2 ○ Positive ○ Negative ○ Not done Test kit:
   → ***Complete Follow-up HIV Positive CRF.***

3. HIV rapid test 3 ○ Positive ○ Negative ○ Not done Test kit:
   → ***Complete Follow-up HIV Positive CRF.***

Pregnancy/STI Test Results

4. HcG for pregnancy ○ Positive ○ Negative ○ Not done
   → ***If positive, complete PREG CRF.***

5. N. gonorrhoeae ○ Positive ○ Negative ○ Not done

6. C. trachomatis ○ Positive ○ Negative ○ Not done

7. T. vaginalis ○ Positive ○ Negative ○ Not done

8. Syphilis RPR ○ Positive ○ Negative ○ Not done

   8a. Titer result: 1: nn ***OR*** ☐ Not available

9. Syphilis TPPA ○ Positive ○ Negative ○ Not done

Clinical Monitoring for PrEP

10. Creatinine clearance nnn *mL/min* ***OR*** ☐ Not done

11. HBsAg ○ Positive ○ Negative ○ Not done

POC Urine Tenofovir

12. Urine tenofovir ○ Positive ○ Negative ○ Not done ☐ File uploaded

CRF 140/085 (POS) PTID: Visit: Visit date:

INSIGHT

nn-nn-nnnn-n | | DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Screening HIV Positive

HIV Test Results

1. HIV EIA antigen/antibody: ◯ Positive ◯ Negative ◯ Indeterminate
2. Site-determined HIV status: ◯ HIV-infected ◯ HIV-uninfected → ***Go to item 6.***

HIV-infected

3. Did the participant know before today that she had HIV?
   - ◯ Yes, participant wanted to confirm their results
   - ◯ Yes, participant did not want to disclose their results
   - ◯ No, participant found out today → ***Go to item 5.***

   3a. When did the participant first find out she had HIV? DD/MMM/YYYY
4. Is the participant taking ART (antiretroviral medication or medication for AIDS)?
   - ◯ Yes
   - ◯ No, participant has taken in the past but not currently taking
   - ◯ No, never taken
5. Was the participant referred for HIV care?
   - ◯ Yes
   - ◯ No
   - ◯ Declined referral

Sample Collection

6. Were specimens collected for recency, STI, and HPV testing? ◯ Yes ◯ No → ***If no, end of form.***

   6a. If yes, specimen ID: nnnnnnnnn

STI Testing

7. N. gonorrhoeae ◯ Positive ◯ Negative ◯ Not done
8. C. trachomatis ◯ Positive ◯ Negative ◯ Not done
9. T. vaginalis ◯ Positive ◯ Negative ◯ Not done
10. Syphilis RPR ◯ Positive ◯ Negative ◯ Not done

    10a. Titer result: 1: nn ***OR*** ☐ Not available
11. Syphilis TPPA ◯ Positive ◯ Negative ◯ Not done

CRF 140/087 (FPOS) | PTID: | Visit: | Visit date:

INSIGHT | nn-nn-nnnn-n | | DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Possible Seroconversion

HIV test results

1. HIV EIA antigen/antibody: ◯ Positive ◯ Negative ◯ Indeterminate

2. HIV RNA PCR: ◯ Not done ◯ < ◯ = ◯ > nnnnnnnnn *viral copies/mL* ***OR*** ☐ *target not detected*

   2a. RNA PCR kit lower limit of detection: ☐ 20 ☐ 40 ***OR*** nnn *viral copies/mL*

3. Absolute CD4+: ◯ Not done nnnn *cells/µL* ***OR*** ☐ *unable to analyze* → ***Go to item 4.***

   3a. CD4%: nn.n % ***OR*** ☐ *not available*

4. Site-determined HIV status: ◯ HIV-infected ◯ HIV-uninfected → ***End of form.***

Antiretroviral resistance results

5. Antiretroviral resistance results *(mark all that apply)*
   - ☐ K65R (mutation associated with TDF resistance)
   - ☐ M184 V (mutation associated with FTC resistance)
   - ☐ Other, specify:
   - ☐ Unable to amplify

Positive HIV rapid test

6. Did the participant know before today that she had HIV?
   - ◯ Yes
   - ◯ No, participant found out today → ***Go to item 7.***

   6a. When did the participant first find out she had HIV? DD/MMM/YYYY

7. Is the participant taking ART (antiretroviral medication or medication for AIDS)?
   - ◯ Yes
   - ◯ No, participant has taken in the past but not currently taking
   - ◯ No, never taken

8. Was the participant referred for HIV care?
   - ◯ Yes
   - ◯ No, specify reason:
   - ◯ Declined referral

CRF 140/101 (BAS-1) | PTID: nn-nn-nnnn-n | Visit: | Visit date: DD/MMM/YYYY

INSIGHT

☐ CRF not administered ☐ Delete CRF; reason:

Behavior Assessment (Sexual), page 1

These are interviewer-administered questions and should be read aloud directly as written.

Many people have a primary or main sexual partner who they have sex with on a regular basis, as well as other partners who they have sex with once or occasionally.

1. At any time during the past 3 months, have you had a primary sex partner? ◯ *Yes* ◯ *No* → ***If no, go to item 13.***

2. Have you had the same primary sex partner for the last 3 months? ◯ *Yes* ◯ *No*

3. How long, in months, have you been with your partner? (Only add the months you were together, remove any months there was a break in the relationship.) nn *# of months*

4. How old is your primary partner? nn *age in years* ***OR*** ☐ *Don't know*

5. Have you talked with your primary sex partner about his HIV status? ◯ *Yes* ◯ *No*

6. What is the HIV status of your primary sex partner? ◯ *HIV positive* ◯ *HIV negative* ◯ *Don't know* → ***Go to item 7.***

   6a. Some people infected with HIV are prescribed medication called antiretrovirals or ARVs by a doctor or a nurse to help them live longer. Is your primary sex partner taking ARVs? ◯ *Yes* ◯ *No* ◯ *Don't know*

7. In the past 3 months, have you had vaginal sex with your primary sex partner? ◯ *Yes* ◯ *No*

8. Do you think your primary sex partner had sex with anyone besides you in the past 3 months? ◯ *Yes* ◯ *No* ◯ *Don't know*

CRF 140/102 (BAS-2) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Behavior Assessment (Sexual), page 2

The following questions are about your primary partner. Please indicate if you strongly agree, agree, disagree, or strongly disagree.

	Strongly Agree	*Agree*	*Disagree*	*Strongly Disagree*
9. Your partner has more control than you do in important decisions that affect your relationship.	◯	◯	◯	◯
10. When you and your partner have an argument, your partner gets his way most of the time.	◯	◯	◯	◯
11. Your partner has more control than you do over whether or not to use condoms.	◯	◯	◯	◯
12. Your partner has more control than you do over whether or not you have sex.	◯	◯	◯	◯

13. Including your primary partner if you have one, how many total sex partners have you had in the past 3 months? nn *# of sex partners* → ***If 00, go to item 22.***

14. In the past 3 months, did you have sex with any new partners? A new partner is someone that you have not had sex with in the past year. ◯ *Yes* ◯ *No*

15. In the past 3 months, have you had sex with a partner who you consider to be a blesser? ◯ *Yes* ◯ *No* ◯ *N/A, no sex partner in the last 3 months*

16. In the past 3 months, have you had a sex partner who you consider to be a casual partner or a friend with benefits? ◯ *Yes* ◯ *No* ◯ *N/A, no sex partner in the last 3 months*

17. In the past 3 months, how many times in total have you had vaginal sex? nnn *# of times* → ***If 000 at enrollment, participant is not eligible.***
If 000 at follow-up, go to item 19.

18. In the past 7 days, how many times did you have vaginal sex? nnn *# of acts*

CRF 140/103 (BAS-3) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Behavior Assessment (Sexual), page 3

19. I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

Was a condom used the last time you had vaginal sex? ◯ *Yes* ◯ *No*

20. In the past 3 months, how many times have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus. nnn *# of times* → ***If 000, go to item 21.***

20a. During the last act of anal sex that you had, was a condom used? ◯ *Yes* ◯ *No*

21. Sometimes women find themselves in situations where they need someone to help them.

In the last 3 months, have you had sex with a man because he provided you with or you expected that he would provide you with any of the following?

(mark all that apply)

☐ *Food*

☐ *Clothes, shoes, accessories*

☐ *Cosmetics*

☐ *Cell phone*

☐ *Item for your child(ren) or family such as clothes, food, school fees*

☐ *Transport, tickets, or money for transport*

☐ *Your own school fees or residence fees*

☐ *Somewhere to stay*

☐ *Cash*

☐ *Airtime*

☐ *Other, specify:*

☐ *Not applicable (do not mark any other selections)*

22. How worried are you about getting pregnant in the next year?

◯ *Not worried* ◯ *A lot of worry*

◯ *Some worry* ◯ *Trying to conceive*

23. How worried are you about getting HIV in the next year?

◯ *Not worried* ◯ *A lot of worry*

◯ *Some worry*

CRF 140/105 (RD) | PTID: nn-nn-nnnn-n | Visit: | Visit date: DD/MMM/YYYY

INSIGHT

☐ CRF not administered ☐ Delete CRF; reason:

Relationship Dynamics

These are interviewer-administered questions and should be read aloud directly as written.

Relationship Dynamics: The next 6 questions are about your relationships with your current or most recent partner. Relationships can have good moments and bad moments, and some of these questions may be difficult to answer. Please remember that your answers will be kept CONFIDENTIAL.

1. In the past 1 year, has any partner punched, slapped, kicked, or bit you, or caused you any type of physical harm? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

2. In the past 1 year, has any partner insulted, ignored, or humiliated you, or yelled at you, or made you feel ashamed or bad about yourself? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

3. In the past 1 year, has any partner forced you to have sex or performed any sexual act, or touched you sexually in any way that you did not want? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

4. In the past 1 year, has any partner made you feel afraid, unsafe, or in danger? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

End of interviewer-administered questions.

5. If any of the above are “Yes”, are any ongoing? ◯ *Yes* ◯ *No*

6. Was a referral to support services provided to the participant? ◯ *Yes* ◯ *No*

CRF 140/107 (FW) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Feelings and Worries

These are interviewer-administered questions and should be read aloud directly as written.

This next set of questions deals with your feelings about HIV. Please indicate if you strongly agree, agree, disagree, or strongly disagree with the following statements.

	Strongly Agree	*Agree*	*Disagree*	*Strongly Disagree*
1. I feel I could be vulnerable to HIV infection in the next 3 months.	◯	◯	◯	◯
2. Imagining myself having HIV in the next 3 months is something I find easy to do.	◯	◯	◯	◯
3. I am concerned that I might have sex with someone who could give me HIV in the next 3 months.	◯	◯	◯	◯
4. I am much more likely to get HIV than my friends in the next 3 months.	◯	◯	◯	◯
5. My sexual behavior gives me a chance of getting HIV in the next 3 months.	◯	◯	◯	◯
6. I feel able to protect myself from getting HIV.	◯	◯	◯	◯
7. I think about my chances of getting HIV whenever I have a new sexual partner.	◯	◯	◯	◯

Many people have a primary or main sexual partner, who they have sex with on a regular basis, as well as other partners who they have sex with once or occasionally. For these next two questions, please think about your primary sexual partner. If you do not have a primary sexual partner, please mark N/A.

	Strongly Agree	*Agree*	*Disagree*	*Strongly Disagree*	*N/A*
8. My sexual partner's behavior gives me a chance of getting HIV in the next 3 months.	◯	◯	◯	◯	◯
9. I trust my sexual partner to keep me free from HIV.	◯	◯	◯	◯	◯

CRF 140/109 (MHS) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Mental Health Screening

These are interviewer-administered questions and should be read aloud directly as written.

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past 1 week.

	Rarely or none of the time (less than 1 day)	*Some or a little of the time (1-2 days)*	*Occasionally or a moderate amount of time (3-4 days)*	*All of the time (5-7 days)*
1. I was bothered by things that usually don't bother me.	○	○	○	○
2. I had trouble keeping my mind on what I was doing.	○	○	○	○
3. I felt depressed.	○	○	○	○
4. I felt that everything I did was an effort.	○	○	○	○
5. I felt hopeful about the future.	○	○	○	○
6. I felt fearful.	○	○	○	○
7. My sleep was restless.	○	○	○	○
8. I was happy.	○	○	○	○
9. I felt lonely.	○	○	○	○
10. I could not "get going".	○	○	○	○

CRF 140/111 (SU-1) PTID: Visit: Visit date:

INSIGHT

nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Substance Use, page 1

These are interviewer-administered questions and should be read aloud directly as written.

The following questions are about alcohol and drugs. For alcohol, we mean beer, wine, spirits, or home or local brew, or cider.

1. Have you drunk any alcohol in the past three months? ◯ *Yes* ◯ *No* → ***If no, go to item 6.***

2. How often do you have a drink containing alcohol?
   - ◯ *Monthly or less*
   - ◯ *2 to 4 times a month*
   - ◯ *2 to 3 times a week*
   - ◯ *4 or more times a week*

3. How many drinks containing alcohol do you have on a typical day when you are drinking?
   - ◯ *1 or 2*
   - ◯ *3 or 4*
   - ◯ *5 or 6*
   - ◯ *7 to 9*
   - ◯ *10 or more*

4. How often do you have six or more drinks on one occasion?
   - ◯ *Never*
   - ◯ *Less than monthly*
   - ◯ *Monthly*
   - ◯ *Weekly*
   - ◯ *Daily*

5. In the past 1 month, did you have a drink containing alcohol just before or during sex? ◯ *Yes* ◯ *No* ◯ *N/A: Did not have sex in the past 1 month*

6. In the past 1 month, has your partner been drunk from alcohol?
   - ◯ *Yes*
   - ◯ *No*
   - ◯ *Don't know*
   - ◯ *N/A, I don't have a partner*

CRF 140/112 (SU-2) PTID: Visit: Visit date:

INSIGHT nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

Substance Use, page 2

7. Have you used any recreational drugs in the past three months? ◯ *Yes* ◯ *No* → ***If no, end of form.***

7a. If yes, which drugs have you used in the past 3 months? *(mark all that apply)*

- ☐ *Cannabis, also called marijuana, pot, grass, dakka, dagga or hash*
- ☐ *Cocaine, also called coke or crack*
- ☐ *Amphetamine-type stimulants, for example, speed, diet pills, Tik/Crystal, Meth or ecstasy*
- ☐ *Inhalants, for example, nitrous, glue, petrol, paint thinner*
- ☐ *Sedatives or sleeping pills, for example, serepax, rohypnol, quaaludes/mandrax*
- ☐ *Hallucinogens, for example, LSD, acid, mushrooms, PCP, Special K*
- ☐ *Opioids, for example, heroin (including nyaope/whoonga), morphine, methadone, etc.*
- ☐ *Prescription drugs for non-prescription purposes, for example, codeine (including cough mixture), efavirenz, valium*
- ☐ *Other, specify:*

CRF 140/115 (IPV) | PTID: nn-nn-nnnn-n | Visit: | Visit date: DD/MMM/YYYY

INSIGHT

☐ CRF not administered ☐ Delete CRF; reason:

Intimate Partner Violence

These are interviewer-administered questions and should be read aloud directly as written.

The next six questions are about experiences you may have had in your lifetime. Some of these may be difficult to answer. Please remember that your answers will be kept CONFIDENTIAL.

1. In your lifetime, has anyone threatened to hurt you or actually physically hurt you? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer* → ***Go to item 2.***

   1a. If yes, has anyone threatened to hurt you or actually physically hurt you in the past year? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

2. In your lifetime, have you been afraid of your partner or someone you live with for whatever reason? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer* → ***Go to item 3.***

   2a. If yes, have you been afraid of your partner or someone you live with for whatever reason in the past year? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

3. Have you been bullied or called a name by anyone? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer* → ***Go to item 4.***

   3a. If yes, have you been bullied or called a name by anyone in the past year? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

4. Has your partner or someone else in your life been very controlling or jealous? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer* → ***Go to item 5.***

   4a. If yes, has a partner or someone else in your life been very controlling or jealous in the past year? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

5. Has anyone physically forced you to have sex (or any sexual contact) when you did not want it? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer* → ***Go to item 6.***

   5a. If yes, has anyone physically forced you to have sex (or any sexual contact) when you did not want it in the past year? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

6. Has anyone ever used the words "I'm going to kill you" in an argument or confrontation? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer* → ***End of form.***

   6a. If yes, has anyone used the words "I'm going to kill you" in an argument or confrontation in the past year? ◯ *Yes* ◯ *No* ◯ *Prefer not to answer*

CRF 140/120 (STIA) PTID: Visit: Visit date:

INSIGHT

nn-nn-nnnn-n DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

STI Assessment

1. Does the participant report experiencing any STI symptoms in the past 7 days? ◯ Yes ◯ No

1a. Was a pelvic exam conducted? ◯ Yes ◯ No

1b. STI symptoms reported/seen today: *(Mark all that apply)*

- ☐ None
- ☐ Discharge
- ☐ Dysuria
- ☐ Genital ulcer
- ☐ Itching
- ☐ Lower abdominal pain
- ☐ Vaginal odor
- ☐ Other, specify:

2. Was STI treatment given today? ◯ Yes ◯ No → ***If no, go to item 3.***

2a. Treatment based on: *(Mark all that apply)*

- ☐ Test results
- ☐ Syndromic management

2b. What treatment was given? *(Mark all that apply)*

- ☐ Acyclovir
- ☐ Amoxicillin
- ☐ Azithromycin
- ☐ Benzathine Penicillin
- ☐ Cefixime
- ☐ Ceftriaxone
- ☐ Clotrimazole
- ☐ Doxycycline
- ☐ Flucanozole
- ☐ Metronidazole
- ☐ Penicillin
- ☐ Probenecid
- ☐ Tinidazole
- ☐ Treatment for genital warts
- ☐ Other, specify:

2c. Treatment given for: *(Mark all that apply)*

- ☐ Bacterial vaginosis
- ☐ Cervicitis
- ☐ Non-vesicular genital ulcers (treatment for syphilis and chancroid)
- ☐ Vesicular genital ulcers (treatment for herpes)
- ☐ Gonorrhoeae
- ☐ Pelvic inflammatory disease
- ☐ Syphilis
- ☐ Trichomonas vaginalis
- ☐ Vaginitis/vaginal candidiasis
- ☐ Other, specify:

3. Is participant aware of partner experiencing STI symptoms? ◯ Yes ◯ No ◯ Don't know

3a. Participant was offered: *(Mark all that apply)*

- ☐ Partner STI treatment
- ☐ Partner letter/referral card
- ☐ Partner declined
- ☐ Not offered

For participants who were offered Partner STI treatment of Partner letter/referral card at a previous visit:

4. Did your partner get tested or take treatment? ◯ Yes ◯ No ◯ Don't know

CRF 140/135 (PDISC) | PTID: | Visit: | Visit date:

INSIGHT | nn-nn-nnnn-n | | DD/MMM/YYYY

☐ CRF not administered ☐ Delete CRF; reason:

PrEP Discontinuation

1. Date of last PrEP use: DD/MMM/YYYY

2. Who initiated the PrEP hold? ☐ Clinician → ***Complete item 2a.*** ☐ Participant → ***Complete item 2b.***

2a. Why is PrEP being held or discontinued by **clinician**? *(mark all that apply)*

- ☐ PrEP-related toxicity/side effects
- ☐ Met CrCl criteria per national guidelines
- ☐ Hepatitis B infection contraindication per national guidelines
- ☐ Clinical reasons determined by the investigator, specify:
- ☐ Reported use of prohibited concomitant medication
- ☐ One or more reactive HIV tests
- ☐ Acute HIV infection suspected
- ☐ Other, specify:

2b. Why is PrEP being held or discontinued by **participant**? *(mark all that apply)*

- ☐ No sexual activity
- ☐ Social impact
- ☐ Difficulty storing the pill
- ☐ Side effects
- ☐ Participant trusts that partner is faithful/ monogamous
- ☐ Choosing a different PrEP option (e.g., dapivirine ring or CAB-LA)
- ☐ Participant preference
- ☐ Difficulty taking the pill
- ☐ Does not want to continue due to pregnancy
- ☐ Partner reports recent/regular HIV testing
- ☐ Other, specify:

3. Date of PrEP resume: DD/MMM/YYYY

OR ☐ not continued at end of study

Visit code at which PrEP resumed: nnnn

CRF 140/138 (HLA) | PTID: nn-nn-nnnn-n | Visit: | Visit date: DD/MMM/YYYY

INSIGHT

☐ CRF not administered ☐ Delete CRF; reason:

HLA Consent and Specimen Collection

HLA Consent

1. Did the participant consent to HLA typing as part of INSIGHT? ◯ Yes ◯ No → ***If no, end of form.***

1a. Date consent marked or signed: DD/MMM/YYYY

Specimen Collection

1b. If yes, was HLA specimen collected? ◯ Yes ◯ No → ***If no, end of form.***

1b1. Sample ID:

Comments:

CRF 140/250 (NPC)

INSIGHT

PTID: nn-nn-nnnn-n

Page #:

Form Completion Date: DD/MMM/YYYY

☐ Delete CRF; reason:

New Protocol Version Consent Log

1. Date participant or guardian re-consented to updated INSIGHT protocol: DD/MMM/YYYY	Visit code:	Protocol version: nn.n	
1a. Date participant re-assented to updated INSIGHT protocol: DD/MMM/YYYY	Visit code:	**OR** ☐ N/A	
2. Date participant or guardian re-consented to updated INSIGHT protocol: DD/MMM/YYYY	Visit code:	Protocol version: nn.n	
2a. Date participant re-assented to updated INSIGHTprotocol: DD/MMM/YYYY	Visit code:	**OR** ☐ N/A	
3. Date participant or guardian re-consented to updated INSIGHT protocol: DD/MMM/YYYY	Visit code:	Protocol version: nn.n	
3a. Date participant re-assented to updated INSIGHT protocol: DD/MMM/YYYY	Visit code:	**OR** ☐ N/A	

SDV ☐ SDV Date:

CRF 140/330 (PREG)

INSIGHT

PTID: nn-nn-nnnn-n

Visit:

Form completion date: DD/MMM/YYYY

☐ Delete CRF; reason:

Pregnancy Report

1. Date of first positive pregnancy test: DD/MMM/YYYY

2. Date of first day of last normal menstrual period: DD/MMM/YYYY **OR** ☐ Unknown ☐ N/A *(no menses in past 6 months)*

3. Estimated date of delivery: DD/MMM/YYYY **OR** ☐ Unknown

4. Comments:

SDV ☐ SDV Date:

CRF 140/342 (P-OUT)

INSIGHT

PTID: nn-nn-nnnn-n

Visit:

Form completion date: DD/MMM/YYYY

☐ Delete CRF; reason:

Pregnancy Outcome

1. Visit code for when pregnancy was reported: nnnn

2. How many fetuses resulted from the pregnancy? ☐ **OR** ☐ Unknown

3. Outcome date: DD/MMM/YYYY **OR** ☐ Outcome not obtainable

4. Specify outcome for first fetus:
   - ◯ Full-term live birth (≥ 37 weeks)
   - ◯ Preterm live birth (< 37 weeks)
   - ◯ Spontaneous abortion (second trimester and < 20 weeks)
   - ◯ Spontaneous abortion (first trimester)
   - ◯ Spontaneous fetal death and/or stillbirth ≥ 20 weeks
   - ◯ Ectopic pregnancy
   - ◯ Therapeutic / elective abortion
   - ◯ Other / unknown, describe:

5. Outcome of second fetus:
   - ◯ N/A, only one baby or unknown number of fetuses
   - ◯ Same outcome as first fetus
   - ◯ Other , describe:

6. Were any fetal/infant congenital anomalies identified? ◯ Yes ◯ No ◯ Unknown

7. Did the participant experience obstetric complications? ◯ Yes ◯ No ◯ Unknown

CRF 140/450 (DV)

INSIGHT

PTID: nn-nn-nnnn-n

Page #:

Form Completion Date: DD/MMM/YYYY

☐ Delete CRF; reason:

Protocol Variance

1. Visit code associated with this protocol variance:
2. Date variance occurred (start date): DD/MMM/YYYY
3. Date of site awareness: DD/MMM/YYYY
4. Type of variance: *(choose from drop-down list)*
5. Was event reported to IRB/IEC? ◯ Yes ◯ No → ***If no, go to item 6.***

   5a. If yes, date reported: DD/MMM/YYYY
6. Provide a brief description of the protocol variance:
7. Plans and/or action taken to address the variance:
8. Date event ended: DD/MMM/YYYY

SDV ☐ SDV Date:

CRF 140/465 (TRAN)

INSIGHT

PTID: nn-nn-nnnn-n

Form Completion Date: DD/MMM/YYYY

☐ Delete CRF; reason:

Participant Transfer

Participant Transfer

1. Site code of transferring study site	nn
2. Site code of receiving study site	nn
3. Visit code of last completed contact with participant at the transferring site	nnnn
4. Date participant records were sent to receiving study site	DD/MMM/YYYY
5. Reason for participant transfer	

SDV ☐ SDV Date:

CRF 140/466 (REC)

INSIGHT

PTID: nn-nn-nnnn-n

Form Completion Date: DD/MMM/YYYY

☐ Delete CRF; reason:

Participant Receipt

Participant Receipt

1.	Site code of receiving study site	nn	
2.	Site code of transferring study site	nn	
3.	Date the participant or guardian marked or signed the study enrollment consent at receiving study site	DD/MMM/YYYY	**OR** ☐ N/A
4.	Date the participant marked or signed the study enrollment assent at receiving study site	DD/MMM/YYYY	**OR** ☐ N/A

SDV ☐ SDV Date:

CRF 140/480 (SH)

INSIGHT

PTID: nn-nn-nnnn-n

Page #:

Form Completion Date: DD/MMM/YYYY

☐ Delete CRF; reason:

Social Harms

If a social harm IS related to study participation or triggered by a study procedure or visit, fill out this full e-form. If a social harm is NOT related to study participation or triggered by a study procedure or visit, fill out items 1 and 1a ONLY on this e-form. All social harms should be captured in the chart notes, regardless of relatedness - to capture social harms in the chart notes use and file a paper version of this form. Contact the Study Safety Monitor if you have questions.

1. Was the social harm related to the participant's participation in the study? ◯ Yes ◯ No

1a. Was detail of the social harm captured in the chart notes? ◯ Yes ◯ No

2. Describe social harm and how it was related to the study and if it was specifically related to PrEP use:

3. Social harm code:

4. Onset date: DD/MMM/YYYY

5. Visit code associated with this social harm:

6. Did this involve physical harm to the participant? ◯ Yes ◯ No

7. Did this involve physical or other harm to the participant's child(ren)? ◯ Yes ◯ No ◯ N/A (no children)

8. What impact did this situation have on the participant's quality of life?
   - ◯ Minimal disturbance
   - ◯ Moderate disturbance, no significant impact
   - ◯ Major disturbance with significant impact

9. Describe what was done by participant and staff to address social harm (from participant chart notes):

10. Record current status:
    - ◯ Unresolved
    - ◯ Unresolved at end of study
    - ◯ Unable to resolve, no further action taken
    - ◯ Resolved
      - → Closure date: DD/MMM/YYYY

11. Was a referral to support services provided to the participant? ◯ Yes ◯ No

SDV ☐ SDV Date:

CRF 140/490 (TERM)

INSIGHT

PTID: nn-nn-nnnn-n

☐ Delete CRF; reason:

Termination

1. Termination date:	DD/MMM/YYYY
2. Reason for termination:	◯ 2a. Scheduled exit/end of study ◯ 2b. Death ***(Notify sponsor)*** → 2.b.i. Date of death: DD/MMM/YYYY **OR** ☐ Unknown → 2.b.ii. Cause of death: **OR** ☐ Unknown ◯ 2c. Ineligible enrollment, specify: ◯ 2d. Investigator decision, specify: ◯ 2e. Protocol variance ◯ 2f. Withdrawal of consent by participant ◯ 2g. Withdrawal of consent by parent or guardian ◯ 2h. Site terminated by sponsor ◯ 2i. Study terminated by sponsor ◯ 2j. Other, specify:
3. Comments:	

SDV ☐ SDV Date: