Plate Number: 001 DEM-1: Demographics: Young Woman

Visit Code: visit

HPTN 068 (183) DEM-1 (001)

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Demographics: Young Woman

DEMstid

Unit/Site ID

Form Completion Date

DEMdt (dd) | (MMM) | (yy)

1. What is the participant's (young woman) date of birth? ..... DEMbthdt (dd) (MMM) (yy) → *If unknown, record age:* DEMage (years)

2. What is your gender? ..... NOT APPLICABLE FOR THIS PROTOCOL. DEMsex ☐ *male* ☐ *female*

3. Mark the appropriate racial category for this participant.

- ☐ DEMblack Black
- ☐ DEMclrd Coloured
- ☐ DEMwhite White
- ☐ DEMindn Indian
- ☐ DEMraco other, specify: DEMracox

bit4b003b002b001_001 18 JAN-11

formlang (Language) sfdt_001 (Staff Initials / Date)

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Demographics: Parent/Guardian

Form Completion Date

DEPdt

dd | MMM | yy

1. What is the Parent/Guardian's Participant ID? ..... DEPpgpid – – – –

   Site Number | Participant Number | Chk | Cohort

2. What is the Parent/Guardian's date of birth? DEPbthdt

   dd | MMM | yy → *If unknown, record age:* DEPage years

3. What is the Parent/Guardian's gender?..... *male* *female* DEPsex ☐

4. Mark the appropriate racial category for the Parent/Guardian.

   DEPblack Black

   DEPclrd Coloured

   DEPwhite White

   DEPindn Indian

   DEPraco other, specify: DEPracox _____

5. Did the Parent/Guardian complete the Baseline Household Questionnaire? ..... *yes* *no* DEPpghhq

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Enrollment

Enrollment Date

ENRdt

dd | MMM | yy

1. Did the participant complete the ACASI Baseline Questionnaire? ..... *yes* *no* ENRacasi

2. Mark the village (village number) where the participant has her permanent residence:

ENRagin Agincourt (101)	ENRjust Justicia A/Justicia B (109)	ENRxan Xanthia (117)
ENRclb Croquet Lawn B (102)	ENRkila Kildare A (110)	ENRkhay Khaya Lami (118)
ENRcl Croquetlawn (103)	ENRkilbc Kildare B/Kildare C (111)	ENRdmpha Dumphries A (119)
ENRcunna Cunningmore A (104)	ENRlilla Lilydale A/Rholane (112)	ENRdmphb Dumphries B (120)
ENRcunnb Cunningmore B (105)	ENRlillb Lilydale B (113)	ENRdmphc Dumphries C (121)
ENRhunt Huntington (106)	ENRnewtb Newington B (114)	ENRirec Ireagh C (122)
ENRirea Ireagh A (107)	ENRnewtc Newington C (115)	ENRsmstc Somerset C (123)
ENRireb Ireagh B (108)	ENRsmsta Somerset A/Somerset B (116)	ENRblfst Belfast (124)
ENRmerry Merrypebble Stream (125)	ENRcork Cork (126)	ENRthul Thulamahashe (127)
ENRrolle Rolle C (125)		
ENRkhum Khumani (125)		

3. What is the grade of the participant at enrollment? ..... ENRgrade *8th grade* *9th grade* *10th grade* *11th grade*

4. Was informed consent for long-term specimen storage signed? ..... *yes* *no* ENRspec

5. Record the Randomization Envelope Number: ..... ENRren

6. Indicate the participant's randomization assignment: ..... ENRra *intervention (conditional cash transfer)* *control (no payments)*

Participant ID

ptid – Site Number – Participant Number – Chk – Cohort

Follow-up Visit

Visit Date

FUVdt (dd / MMM / yy)

1. Did the participant complete the ACASI Follow-up Questionnaire? ..... FUVacasi (yes / no)

2. Since the last visit, has the participant experienced any social harms as a result of participation in this study? FUVsh (yes / no)

   If yes, complete Social Impact Log.

3. Since the last visit, did the participant change her village of permanent residence? ..... FUVvilch (yes / no)

   If no, go to item 4.

   3a. Record new Village Number: ..... FUVvilln

   If 125, specify village: FUVvills
   - Merrypebble Stream
   - Rolle C
   - Khumani

4. Since the last visit, has there been a change in the participant's Parent/Guardian of record? ..... FUVpgch (yes / no)

   If no, go to item 5.

   4a. Was a Demographics: Parent/Guardian CRF submitted for this parent/guardian at a previous visit? FUVpgdep (yes / no)

   If no, complete Demographics: Parent/Guardian. Go to item 5.

   4b. Record Parent/Guardian ID: ..... FUVpgpid – Site Number – Participant Number – Chk – Cohort

5. Did the Parent/Guardian complete the Follow-up Household Questionnaire? ..... FUVpghq (yes / no)

Participant ID

ptid – – – –

Site Number Participant Number Chk Cohort

Virology Test Results

Initial Specimen Collection Date

VTRdt

dd MMM yy

1. Specimen Collection for Storage

		stored	not stored	reason not stored:
1a.	Plasma	VTRpls	→	VTRplsr
1b.	Dried blood spot	VTRdbs	→	VTRdbpr

VTRhiv *Mark this box if participant was previously confirmed HIV+. End of form. End of form.*

2. HSV-2 Assay

No longer recorded on the VTR-1. See HSV-1 form.

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		negative	positive	
VTRhsv	VTRhsvdt				VTRhsv		VTRhsv

3. HIV Test Results

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		kit code		negative	positive	
VTRrap	VTRrapdt			3a. Rapid test 1	VTR1rt	.....	VTRrap		VTRra
VTR2rap	VTR2rpdt			3b. Rapid test 2	VTR2rt	.....	VTR2rap		VTR2r

If one or both are positive, complete HIV Confirmatory Test Results.

Comments: VTRcomm

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

HSV-2 Test Result

Specimen Collection Date

HSVdt

dd *MMM* *yy*

negative *positive* *not done*

1. HSV-2 Result HSVhsv → *If not done, specify reason in Comments.*

Comments: HSVcomm

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14-FEB-12

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Language

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Staff Initials / Date

Participant ID

ptid – – – –

Site Number Participant Number Chk Cohort

HIV Confirmatory Test Results

Sample 1

1. Absolute CD4+ (cells/mm3) HTRcd4

2. HIV Western Blot ..... negative / positive / indeterminate HTRwb1

If negative or indeterminate, contact Network Lab.

If positive, go to Sample 2: item 3.

3. Sample 2 ..... Not done/Not collected HTR2nd; Specimen Collection Date dd MMM yy HTR2cldt

If not done/not collected, go to Sample 3: Item 4.

3a. HIV Western Blot negative / positive / indeterminate HTRwb2

If negative or indeterminate, contact Network Lab.

3b. Plasma Storage ..... stored / not stored HTR2pls Reason: HTR2plsx

3c. Dried Blood Spot Storage HTR2dbs HTR2dbsx

4. Sample 3 ..... Not done/Not collected HTR3nd; Specimen Collection Date dd MMM yy HTR3cldt

If not done/not collected, go to item 5.

4a. HIV Western Blot negative / positive / indeterminate HTRwb3

If negative or indeterminate, contact Network Lab.

4b. Plasma Storage ..... stored / not stored HTR3pls Reason: HTR3plsx

4c. Dried Blood Spot Storage HTR3dbs HTR3dbsx

5. Final HIV status: ..... negative / positive / other, specify: HTRfin HTRfinx

Comments: HTRcomm

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Language Staff Initials / Date

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Social Impact Log

1. Concisely describe social impact related to study participation experienced by the participant:

SILsumx

2. Onset date: ..... SILondt (dd) (MMM) (yy)

3. Reported at visit:..... SILatvis

4. Social impact code: SILcode

5. Social impact grade:

Grade 1: mild	Grade 2: moderate	Grade 3: severe	Grade 4: potentially life-threatening
SILgrade	☐	☐	☐

Social Impact Codes: *See back for definitions.*

01 Personal Relationships
02 Travel/Immigration
03 Employment
04 Education
05 Medical/Dental
06 Health Insurance
07 Life Insurance
08 Housing
09 Military/Other Government Agency
10 Other
11 Harassment, bullying, coercion
12 Violence
13 Sexual

Plate Number: 155 FCD-1: Follow-up CD4 Test Result

Visit Code visit

HPTN 068 (183) FCD-1 (155)

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Follow-up CD4 Test Result

Specimen Collection Date

FCDdt

dd | MMM | yy

1. Absolute CD4+ FCDcd4 *cells/mm3*

FCDcd4n *not done*

If not done, specify reason in Comments.

Comments: FCDcomm

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14-FEB-12

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Staff Initials / Date

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Participant ID

ptid – – – – – –

Site Number Participant Number Chk Cohort

Graduation Visit

Visit/Form Completion Date

GVdt

dd MMM yy

GVlav ☐ ***Mark this box if visit was completed and was a Limited Assessment. Complete LAV-1, ESI-1, and TM-1 (mark reason 2a). End of form.***

1. Did the participant complete this visit?

GVcmplt ☐ yes ⟶ ***If yes, complete VTR-1, ESI-1, and TM-1 (mark reason 2a). Complete HSV-1 and/or FCD-1, if applicable. End of form.***

☐ no ⟶ ***If no, complete TM-1 and ESI-1.***

1a. If no, indicate reason. ***Mark only one.***

GVrsn ☐ participant refused

☐ participant lost to follow-up

☐ previous visit was too recent

☐ participant deceased

☐ other, specify: GVrsnotx _____

Comments: GVcomm _____

Plate Number: 230 PIV-1: Post-intervention Visit

Visit Code: visit

HPTN 068 (183) (PIV-1) 230

Participant ID

ptid – Site Number – Participant Number – Chk – Cohort

Post-intervention Visit

Visit/Form Completion Date

PIVdt (dd MMM yy)

1. Was the post-intervention visit completed? PIVcmplt yes / no → *If yes, go to item 2.*

1a. If no, why wasn't the visit completed? ***Mark only one. End of form.***

PIVrsn
- unable to contact participant
- participant refused visit
- participant incarcerated
- participant deceased
- investigator decision, specify: PIVrsnid
- other, specify: PIVrsnox

2. Was a limited assessment visit conducted at this post-intervention visit? PIVlav yes / no → *If yes, complete the Post-Intervention Limited Assessment Visit form.*

3. Did the participant complete the ACASI Young Woman Questionnaire? PIVacasi

4. Did the participant complete the Household Questionnaire? PIVhhq

5. Since the last visit, has the participant experienced any social harms as a result of participation in this study? PIVsh yes / no → *If yes, complete Social Impact Log.*

6. Since the last visit, did the participant change her village of permanent residence? PIVvilch yes / no → *If no, go to item 7.*

6a. Record new Village Number: PIVvilln → *If 125, specify village:* PIVvills
- Merrypebble Stream
- Rolle C
- Khumani

7. Blood Pressure:

7a. Blood Pressure–1st measurement: PIVbp1s / PIVbp1d mmHg OR PIVbp1n Not done

7b. Blood Pressure–2nd measurement: PIVbp2s / PIVbp2d mmHg OR PIVbp2n Not done

7c. Blood Pressure–3rd measurement: PIVbp3s / PIVbp3d mmHg OR PIVbp3n Not done

8. Height: ..... PIVht . cm OR PIVhtn Not done

9. Weight: ..... PIVwt . kg OR PIVwtn

10. Waist Circumference: ..... PIVwst . cm OR PIVwstn

11. BMI: ..... PIVbmi . kg/m^2 OR PIVbmin

12. Was informed consent for long-term specimen storage signed? ..... PIVspec yes / no

Comments: PIVcomm

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Limited Assessment Visit

Initial Specimen Collection Date

LAVdt

dd | MMM | yy

1. Were HIV rapid tests performed by finger stick? ..... yes LAVrap / no → *If no, do not complete form. Do not fax to SCHARP DataFax.*

1a. Dried blood spot storage..... stored LAVdbs / not stored → Reason not stored: LAVdbsr

1b. HIV Test Results

	kit code	negative	positive
1b1. Rapid test 1	LAVkit1	LAVrap1	
1b2. Rapid test 2	LAVkit2	LAVrap2	

Alternate Collection Date

dd | MMM | yy

LAVhivdt

2. Was a venous blood draw done? yes LAVvbd / no → *If no, end of form.*

2a. HIV Western Blot ..... negative / positive / indeterminate LAVwb → *If negative or indeterminate, contact Network Lab.*

2b. Plasma storage ..... stored LAVpls / not stored → Reason not stored: LAVplsr

Comments: LAVcomm

Participant ID

ptid [ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]

Site Number Participant Number Chk Cohort

Post-intervention Limited Assessment Visit

Initial Specimen Collection Date

PLVdt [ ][ ] [ ][ ][ ] [ ][ ]

dd MMM yy

1. Were HIV rapid tests performed by finger stick? ..... yes PLVrap [ ] no → *If no, do not complete form. Do not fax to SCHARP DataFax.*

1a. Dried blood spot storage ..... stored PLVdbs [ ] not stored → Reason not stored: PLVdbsr _____

1b. HIV Test Results

1b1. Rapid test 1 ..... kit code PLVkit1 [ ][ ] negative PLVrap1 [ ] positive [ ]

1b2. Rapid test 2 ..... PLVkit2 [ ][ ] PLVrap2 [ ] [ ]

Alternate Collection Date

dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

2. Was a venous blood draw done? yes PLVvbd [ ] no → *If no, end of form.*

2a. HIV Western Blot ..... negative PLVwb [ ] positive [ ] indeterminate [ ] → *If negative or indeterminate, contact Network Lab.*

2b. Plasma storage ..... stored PLVpls [ ] not stored → Reason not stored: PLVplsr _____

Comments: PLVcomm _____

Participant ID

ptid

Site Number – Participant Number – Chk – Cohort

Interim Visit

Visit Date

IVdt

dd MMM yy

1. What is the reason for this interim visit? *Mark all that apply.*

IVpgch change in Parent/Guardian

1a1. Was a Demographics: Parent/Guardian CRF submitted for this parent/guardian at a previous visit? ..... yes no IVpgdep → ***Complete Demographics: Parent/Guardian. Go to item 1b.***

1a2. Record Parent/Guardian ID: ..... IVpgpid

Site Number – Participant Number – Chk – Cohort

IVvilch change in participant's village of permanent residence → *If 125, specify village:*

1b1. Record new Village Number: ..... IVnvill

IVvills ☐ Merrypebble Stream ☐ Rolle C ☐ Khumani

IVsh c. to report social harm(s) → ***Complete Social Impact Log.***

IVhiv d. HIV testing → ***Complete Virology Test Results.***

IVcd4 e. follow-up CD4 testing → ***Complete Follow-up CD4 Test Results.***

IVhsv f. HSV testing → ***Complete HSV-2 Results.***

IVoth g. other, specify: IVothx _____

Plate Number: 463 MV-1: Missed Visit Visit Code visit.

HPTN 068 (183) MV-1 (463)

Participant ID

ptid – – – –

Site Number Participant Number Chk Cohort

Missed Visit

Form Completion Date

MVfcdt dd MMM yy

1. Target Visit Date: MVtdt dd MMM yy

2. Reason visit was missed. *Mark only one.*

MVreasn

- 2a. unable to contact participant
- 2b. unable to schedule appointment(s) within target window
- 2c. participant refused visit
- 2d. participant incarcerated
- 2e. participant admitted to a health care facility
- 2f. participant withdrew from the study → ***Complete a Termination form.***
- 2g. participant deceased → ***Complete a Termination form.***
- 2h. other, specify:

MVotrex

Comments: MVcomm

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Language Staff Initials / Date

Participant ID

ptid – – –

Site Number | Participant Number | Chk | Cohort

Participant Incident Log — For Internal Use Only

dd *MMM* *yy*

Form Completion Date: PILdt

Study Project Manager: PILstpm

If applicable: **Plate #:** PILplate

Visit/Page #: PILvisit

Incident: *Mark all that apply*

- PILenrol inappropriate enrollment/ineligible
- PILrand randomization
- PILhivts HIV testing
- PILprotd protocol deviation/event
- PILinco other, specify: PILincox
- PILprots [protocol-specific reason]

Details: *Provide additional information, including date(s), site(s), lab(s), outcome, etc. as appropriate.*

PILdtlsx

Plate Number: 489 ESI-1: End of Study Inventory

Visit Code: visit

HPTN 068 (183) ESI-1 (489)

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

End of Study Inventory

Form Completion Date

ESIdt

dd | MMM | yy

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax?..... *visit code* ESIlvis

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?..... *# of interim visits* ESIivis

3. Indicate the **highest** page number submitted for this participant for the Social Impact Log:

3a. Social Impact Log (SIL-1) ..... *page #* ESIsilpg OR *no pages submitted* ESIsilpn

Comments: ESIcomm

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formlang Language

sfdt_489 Staff Initials / Date

Participant ID

ptid – – – –

Site Number | Participant Number | Chk | Cohort

Termination

1. Termination Date: dd TMtmdt | MMM | yy — *Date the site determined that the participant was no longer in the study.*

2. Reason for termination. *Mark only one.*

- ☐ TMtrmrsn 2a. scheduled exit visit/end of study → ***End of form.***
- ☐ 2b. death, *indicate date and cause if known*
  - 2b1. date of death: dd TMddt | MMM | yy — OR ☐ TMddun date unknown
  - 2b2. cause of death: TMdcau — OR ☐ TMdcun cause unknown
- ☐ 2c. participant refused further participation, specify: TMrefrx
- ☐ 2d. participant unable to adhere to visit schedule
- ☐ 2e. participant relocated, no follow-up planned
- ☐ 2f. investigator decision, specify: TMinvdx
- ☐ 2g. unable to contact participant
- ☐ 2h. HIV infection — NOT APPLICABLE FOR THIS PROTOCOL.
- ☐ 2i. inappropriate enrollment
- ☐ 2j. invalid ID due to duplicate screening/enrollment
- ☐ 2k. other, specify: TMtrmox
- ☐ 2l. early study closure

Comments: TMcomm