





Plate 011 IS-1: Index Screening Assessment

Visit Code

HPTN 037 IDU Networks (095) IS-1 (011)

Page 1 of 1

Index Screening Assessment

Index Screening Assessment

Participant ID

-  -   -

Site Number Participant Number Chk Network ID Member

Form Completion Date

dd/mm/YY dd MMM yy

Recruitment Location

1. Are you at least 18 years of age? .....

yes no

2. Have you ever injected drugs?.....

If no to either, participant is ineligible.

2a. In the last 3 months (that is, since \_\_\_\_\_), how many times total have you injected drugs? .....

If < 12, participant is ineligible.

3. Thinking about the people that you know or hang out with, how many of these people do you usually buy drugs with or shoot up with? .....

4. Thinking about the people that you know or hang out with, how many of these people do you have sex with? .....

5. How many of these people that you do drugs with or have sex with are you willing to bring in to join this study?.....

If < 2, participant is ineligible.

6. Have you ever been in methadone maintenance treatment? .....

yes no

If no, go to item 7.

6a. Have you been out of methadone maintenance treatment for at least 3 months?.....

If no, participant is ineligible.

7. Are you currently a participant in any other HIV prevention research study or have you been in another HIV prevention study in the last 6 months? .....

If yes, participant is ineligible.

Plate 012 IC-1: Index Eligibility Checklist

Visit Code **visit**

HPTN 037 IDU Networks (095) IC-1 (012)

Page 1 of 1

Index Eligibility Checklist

Index Eligibility Checklist

Participant ID

ptid - NKID - MRID

Site Number Participant Number Chk Network ID Member

Form Completion Date

ICdt dd/mm/yy

dd MMM yy

Inclusion

1. Is the participant of legal age to provide written informed consent for research? See item 1, DM-1. ....

yes no  
 ICageck

2. Did the participant provide written informed consent for screening and study participation? .....

ICinfck

2a. Date screening consent signed: ICscrecdt dd/mm/yy

2b. Date study consent signed: ICstudcdt dd/mm/yy

If no to any, participant is ineligible.

3. Does the participant report having injected drugs at least 12 times in the last 3 months? See item 2a, IS-1. ....

yes no  
 ICinjck

4. Has the participant been out of methadone maintenance treatment for at least 3 months and relapsed? See items 2 and 6, IS-1. ....

ICoutck

5. Is the participant HIV-seronegative by licensed ELISA? .....

ICshivck

6. Did the participant recruit at least two HIV risk network members who are eligible for study participation? .....

ICmembck

If no to any, participant is ineligible.

Exclusion

7. Is the participant concurrently enrolled or has he or she been previously enrolled in another HIV behavioral or biomedical prevention study in the last 6 months? See item 7, IS-1. ....

yes no  
 ICstudy

8. Does the participant have any obvious psychological disturbance or cognitive impairments that would limit his or her ability to understand study procedures (as determined by clinic staff)? .....

ICpsych

9. Does the participant have, in the opinion of the investigator, any other condition that would make participation in the study unsafe or otherwise interfere with study objectives? .....

ICcondi

10. Is the participant enrolled as a network member or index participant in another HPTN 037 study network? .....

ICnetwrk

If yes to any, participant is ineligible.



Plate 022 MC-1: Member Eligibility Checklist

Visit Code **visit**

HPTN 037 IDU Networks (095) MC-1 (022)

Page 1 of 1

Member Eligibility Check-

list **Member Eligibility Checklist**

Form Completion Date

MCdt      
 dd/mm/YY  
 dd MMM yy

**Participant ID**

ptid    -     -  **NKID**   - **MRID**    
 Site Number Participant Number Chk Network ID Member

**Inclusion**

1. Is the participant of legal age to provide written informed consent for research? *See item 1, DM-1.* .....
2. Has the participant been recruited for the study by an eligible index participant? .....
3. Does the participant report having injected drugs with and/or having had sex with the relevant index participant within 3 months prior to screening? *See items 3 and 4, MS-1.* .....
4. Did the participant provide written informed consent for study participation? .....

yes no

MCageck

MCreprt

MCdrgsex

MCinfc

4a. Date study consent signed:

MCstucdt        
 dd/mm/YY  
 dd MMM yy

*If no to any, participant is ineligible.*

**Exclusion**

5. Does the participant have any obvious psychological disturbance or cognitive impairments that would limit his or her ability to understand study procedures (as determined by clinic staff)? .....
6. Does the participant have, in the opinion of the investigator, any other condition that would make participation in the study unsafe or otherwise interfere with study objectives? .....
7. Is the participant enrolled as a network member or index participant in another HPTN 037 study network? .....

yes no

MCpsych

MCcondi

MCnetwrk

*If yes to any, participant is ineligible.*

Plate 051 SS-1: Screening HIV Status

Visit Code

HPTN 037 IDU Networks (095) SS-1 (051)

Page 1 of 1

Screening HIV Status

Form Completion Date

Participant ID

Screening HIV Status

dd/mm/yy *dd MMM yy*

-  -        
Site Number Participant Number Chk Network ID Member

*dd MMM yy*

1. Date of initial HIV specimen collection: .....      
dd/mm/yy

*negative positive*

2. Participant's HIV status: .....

Plate 101 RE-1: Randomization/Enrollment

Visit Code

HPTN 037 IDU Networks (095) RE-1 (101)

Page 1 of 1

Randomization/Enrollment

Randomization/Enrollment

Form Completion Date

REdt     
 dd / mmm / yy

Participant ID

ptid    -     -    
 Site Number Participant Number Chk NKID MRID

1. Is the participant eligible for the study based on the Eligibility Checklist (IC-1 or MC-1)? .....

yes no  
 REcklst

2. Was the initial date of HIV specimen collection within 60 days prior to randomization? See item 1, SS-1. ....

RE60days

3. Was the index participant randomized? .....

REixrand

3a. Date of randomization: .....

REranddt        
 dd / mmm / yy  
 dd MMM yy

If no to any, end of form.

Item 3b for index participants only. If participant is a network member, end of form.

3b. Randomization envelope number: .....

REenvno    -

















Plate 141 NN-1: Network Norms

Visit Code

HPTN 037 IDU Networks (095) NN-1 (141)

Page 1 of 1

Network Norms

Form Completion Date

Participant ID

-  -  -  -   
 Site Number Participant Number Chk Network ID Member  
 Do not use at follow-up visits

dd/mm/YY  
 dd MMM yy

*Read to participant:* These questions ask about your perception of, or what you think about, the people that you know or hang out with. *Show Card #5.*

	<i>all</i>	<i>most</i>	<i>about half</i>	<i>some</i>	<i>none</i>	<i>don't know</i>
1. How many of your friends who shoot drugs use a needle after someone else, without bleaching or cleaning? .....	<input type="checkbox"/> <b>NNndl</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How many of your friends who shoot drugs use a cooker that someone else has already used? .....	<input type="checkbox"/> <b>NNcooker</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. How many of your friends who shoot drugs use filter cotton that someone else has already used? .....	<input type="checkbox"/> <b>NNcotton</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How many of your friends who shoot drugs use drugs that are frontloaded or backloaded with a shared syringe?.....	<input type="checkbox"/> <b>NNload</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How many of your friends have sex with more than one person? .....	<input type="checkbox"/> <b>NNsexmp</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. How many of your friends use condoms all the time with their primary partner (husband, wife, boyfriend, or girlfriend)? .....	<input type="checkbox"/> <b>NNcondalw</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How many of your friends approve of condom use with a primary partner?.....	<input type="checkbox"/> <b>NNacpp</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How many of your friends use condoms all the time with their casual or occasional partners? .....	<input type="checkbox"/> <b>NNuccop</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How many of your friends approve of condom use with casual or occasional partners?.....	<input type="checkbox"/> <b>NNaccop</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. How many of your friends encourage you to use condoms with a primary partner?.....	<input type="checkbox"/> <b>NNecpp</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. How many of your friends encourage you to use condoms with casual or occasional partners? .....	<input type="checkbox"/> <b>NNeccop</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. How many of your friends trade sex for money or drugs? .....	<input type="checkbox"/> <b>NNtrade</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12a. How many of your friends who trade sex use condoms all the time with their paying partners? .....	<input type="checkbox"/> <b>NNtrduc</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. How many of your friends pay others for sex?.....	<input type="checkbox"/> <b>NNpaysx</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13a. How many of your friends who pay for sex use condoms every time with the partners that they pay? .....	<input type="checkbox"/> <b>NNpayuc</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*If none or don't know, go to item 13.* ←

*If none or don't know, end of form.* ←

10-MAR-03

postscript—English

formlang

Language Staff Initials / Date

Plate 151 LL-1: Follow-up Local Lab Results

Visit Code

HPTN 037 IDU Networks (095) LL-1 (151)

Participant ID

-  -

Site Number Participant Number Chk

Follow-up Local Lab Results

Follow-up Local Lab Results

SAMPLE 1

Not Done/  
Not Collected Specimen Collection Date

dd/mmm/yy

dd MMM yy

negative positive indeterminate  
1. HIV EIA .....      
If negative, end of form. ←

SAMPLE 2

Not Done/  
Not Collected Specimen Collection Date

dd/mmm/yy

dd MMM yy

negative positive indeterminate  
2. Western Blot/IFA .....      
If negative, end of form. ←

SAMPLE 3

Not Done/  
Not Collected Specimen Collection Date

dd/mmm/yy

dd MMM yy

negative positive indeterminate  
3. Western Blot/IFA .....      
If negative or positive, end of form. ←

LLcommx

Comments: \_\_\_\_\_



Plate 171 SIA-1: Social Impact Assessment

Visit Code

HPTN 037 IDU Networks (095) SIA-1 (171)

Participant ID

-  -

Site Number Participant Number Chk

Social Impact Assessment

Social Impact Assessment

Contact Date

dd/mm/YY dd MMM yy

**Instruction:** Before administering this assessment, update information about any unresolved previously reported social impacts on the corresponding Social Impact Log (SIL).

1. Because of your participation in this study, did anything negative or bad happen to you in the last 6 months? .....  <sup>yes</sup>  <sup>no</sup> **SIAbad**  → If no, go to item 3.

2. Because of your participation in this study, have you... *If yes, how many times?*

2a. been arrested or had trouble with the police or other legal problems?.....  <sup>yes</sup>  <sup>no</sup> **SIApolic**  →  **SIAnpoli**

2b. had trouble getting or keeping housing?.....  **SIAnhouse**  →  **SIAnhouse**

2c. had trouble getting or keeping a job or trouble with income or economic support?.....  **SIAnjob**  →  **SIAnjob**

2d. had trouble getting health care or with health insurance?.....  **SIAnhlth**  →  **SIAnhlth**

2e. had personal trouble with friends, family, or acquaintances?.....  **SIAnfamily**  →  **SIAnfamily**

2f. had any other type of problem? Specify:  
**SIAnotherx**  →  **SIAnother**

Complete a separate Social Impact Log (SIL) for each impact. ← total number of impacts  **SIAnatot**

3. In the last 6 months, has your participation in this study had a positive or beneficial impact on your life? .....  <sup>yes</sup>  <sup>no</sup>  <sup>don't know</sup> **SIAngood**  → If no or don't know, end of form.

3a. If yes, please describe: Summarize participant's response.  
**SIAngoodx**

Plate 181 SIL-1: Social Impact Log

Visit Code **visit**

Page

HPTN 037 IDU Networks (095) SIL-1 (181)

Social Impact Log

Participant ID

**ptid**  -  -

Site Number Participant Number Chk

Social Impact Log

**Instructions:** Fax this form to SCHARP DataFax whenever a new Social Impact is recorded or information on this form is updated. Fax only pages with new entries or revisions.

1. Concisely describe social impact:

**SILdesx**

---



---



---



---

6. Describe what was done by staff and participant to address social impact:

6a. Participant: **SILpptx**

---



---



---



---

2. Onset Date:

**SILondt**  
 dd/mm/yy

6b. Staff: **SILstfx**

---



---



---



---

3. Reported at Visit:

**SILvisit**  
 n.n

4. Social Impact Code:

**SILicode**

Social Impact Codes:	
01 Police/Legal Problems	04 Health Care/Insurance
02 Housing	05 Friends/Family
03 Employment	06 Other

**Ask Participant:**

5. What impact has this situation had on your quality of life?

**SILqol**

Minimal disturbance

Moderate disturbance. No significant impact.

Major disturbance with significant impact.

7. Record current status:

**SILstat**

Unresolved

Unresolved at end of study

Unable to resolve. No further action taken.

Resolved

↓

**If either is marked, enter closure date:**

**SILclsdt**  
 dd/mm/yy

**p181v17**

Reviewed by Investigator: \_\_\_\_\_  
 Principal Investigator (or designee) Signature Date

Plate 191 PV-1: Post-test Visit

Visit Code

HPTN 037 IDU Networks (095) PV-1 (191)

Page 1 of 1

Post-test Visit

Post-test Visit

Form Completion Date

Participant ID

<b>ptid</b>							
Site Number	Participant Number				Chk		

<b>NKID</b>					<b>MRID</b>		
Network ID				Member			

Do not use at follow-up visits

<b>PVdt</b>				
dd/mm/YY	MMM		yy	
dd	MMM		yy	

1. Did the participant receive HIV test results? .....  *yes*  *no*  
**PVreslts**

2. Did the participant receive HIV post-test and risk-reduction counseling? .....  *yes*  *no*  
**PVcounsl**

Plate 451 IPT-1: Intervention Cohort Participant Transfer Visit Code

HPTN 037 IDU Networks (095) IPT-1 (451) Page 1 of 1

**Participant ID**

-  -

Site Number      Participant Number      Chk

Intervention Cohort Participant Transfer

**Intervention Cohort Participant Transfer**

**Form Completion Date**

dd/mm/yy      dd      MMM      yy

**Instructions:** Complete this form when an intervention participant transfers to another cohort.

1. Group ID of transferring cohort:  -

Site Number      Group

2. Group ID of receiving cohort:  -

(add to this group)      Site Number      Group

3. Reason participant failed to attend original cohort session: *Mark only one.*

- incarceration
- hospitalization/illness
- transportation difficulties
- scheduling problem, specify:
- other, specify:
- unknown



Plate 463 MV-1: Missed Visit

Visit Code

HPTN 037 IDU Networks (095) MV-1 (463)

Participant ID

Missed Visit

Form Completion Date

-  -   
Site Number Participant Number Chk

Missed Visit

dd/mm/YY dd MMM yy

**Instructions:** Complete this form when a participant has missed a scheduled visit according to Study Specific Procedures. For Visit Code, enter the visit code of the scheduled visit that was missed. Fax the form to SCHARP DataFax according to the timeline included in the Study Specific Procedures.

Reason Visit Missed:

Mark only one.

dd MMM yy

**MVreasn**

Unable to contact participant; date of last contact with participant:

dd/mm/YY

Missed scheduled appointment(s).

Refused visit.

Incarcerated.

Institutionalized.

Withdrawn from the study. —> **Complete a Termination form.**

Deceased. —> **Complete a Termination form.**

Other, please specify: **MVotherx**

Comments:

**MVcommx**

---

---

---

---

---

---

---

---

Plate 487 PIL: Participant Incident Log

Page 

visit
nn

HPTN 037 IDU Networks (095)

PIL-1 (487)

Participant Incident Log

Participant ID

ptid									
------	--	--	--	--	--	--	--	--	--

  
Site Number      Participant Number      Chk

Participant Incident Log –  
For Internal Use Only

Form Completion Date: 

PILfcdt					
dd/mm/YY					

Subject: Mark all that apply.

SC Staff Name: 

PILstaff
----------

PILforms  
forms

Source of Information: 

PILsourc
----------

PILprot  
protocol

If applicable:

Plate #: 

PILplate			
----------	--	--	--

PILdata  
data

PILlab  
lab

Visit: 

PILvisit					
----------	--	--	--	--	--

PILenrol  
enrollment

PILrand  
randomization

PILsubo  
Other, specify: 

PILsubox
----------

Event and resolution details:

PILevnt

---

---

---

---

---

---

---

---

---

---

---

---

--	--	--	--

				11-JUL-03
--	--	--	--	-----------

--	--

Language

--

Staff Initials / Date



Plate 489 ESI-1: End of Study Inventory

Visit Code  visit

HPTN 037 IDU Networks (095) ESI-1 (489)

Page 1 of 1

Participant ID

End of Study Inventory

Form Completion Date

ptid  -     -   
Site Number Participant Number Chk

End of Study Inventory

ESIdt       
dd MMM yy

1. What is the visit code of the participant's last visit? ..... Visit Code   .

2. What was the last Social Impact Log (SIL-1) page number submitted for this participant? .....   page # OR  none

3. How many Follow-up Local Lab Results forms (LL-1) were submitted for this participant? .....   # of LL-1

Plate 490 TM-1: Termination

Visit Code

HPTN 037 IDU Networks (095) TM-1 (490)

Page 1 of 1

Participant ID

Termination

Form Completion Date

ptid  -  -   
Site Number Participant Number Chk

Termination

TMdt      
dd/mm/yy dd MMM yy

Instructions: Complete this form when a participant terminates from the study.

1. Termination Date:        
dd MMM yy TMtermdt dd/mm/yy

Date the site determined that the participant was no longer in the study.

2. Reason for termination. Mark only one.

2a. Scheduled exit visit/End of study. **TMreasn**  If scheduled exit visit/end of study, end of form.

2b. Death. Indicate date and cause if known.

2b1. Date of death       OR  Date unknown  
dd MMM yy TMdddt dd/mm/yy TMddunk

2b2. Cause of death:  OR  Cause unknown  
TMcsdthx TMcsunk

2c. Participant refused further participation. Specify reason in Comments field.

2d. Participant unable to adhere to visit schedule.

2e. Participant relocated, no follow-up planned.

2f. Investigator decision, please specify: **TMinvdcx**

2g. Unable to contact participant.

2h. HIV infection.

2i. Inappropriate enrollment.

2j. Invalid ID due to duplicate screening/enrollment.

2k. Other reason, please specify: **TMotherx**

3. Was the reason for termination associated with a social harm?

yes no don't know  
    
TMsocimp

3a. Social Impact Log pages:      
page # page # page # TMsilpg1 TMsilpg2 TMsilpg3

If no or don't know, end of form.

Comments:

**TMcomm**