Expiration Date: XX/XX/XXXX

# Identification of behavioral and clinical predictors of early HIV infection

(Project DETECT)

#### **Attachment 8a**

Phase 2 Behavioral Survey (English)

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-1100)

## **Privacy Act Statement:**

This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will only be used by the Centers for Disease Control and Prevention (CDC) staff to: 1) characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care (POC), relative to each other and to currently used gold standard, non-POC tests, and 2) identify behavioral and clinical predictors of early HIV infection.

FP-1 Study ID:
FP-2 Visit Date: MM/DD/YYYY
FP-3 Date of First Visit (Day 0): MM/DD/YYYY
FP-4 Reason for Final Visit:  Day 70
Concordant tests
In this survey we will be asking questions similar to the ones that were asked the day you first tested for HIV in this study on [Fill in date of Part 2 testing/Questionnaire]. In these questions we want to know about things that have happened in the time since [Fill in date of Part 2 testing/Questionnaire].
<b>SUBSTANCE USE</b> The next set of questions is about drugs that weren't prescribed for you by a doctor, sometimes called recreational drugs, that you have taken in the last 3 months.
DU-1 Have you used poppers since your first study visit on [insert date]?  Yes  No
DU-2 Since your first study visit on [insert date], have you injected drugs other than those prescribed by a medical provider?  Yes  No
[If DU-2=YES:] DU-3 Which drugs have you injected?  Heroin Cocaine Methamphetamine (meth or crystal) Other
DU-4 Have you used cocaine since your first study visit on [insert date]?  Yes  No
DU-5 Have you used methamphetamine since your first study visit on [insert date]? Yes No
DU-6 Have you used Viagra, Cialis or Levitra since your first study visit on [insert date]?  Yes  No

#### STD HISTORY

The next set of questions will be about sexually transmitted diseases other than HIV that you may have had since your first study visit.

SD-1 Since your first study visit on [*insert date*], has a health care provider told you that you had an STD other than HIV?

Yes

No

SD-2 You said a healthcare provider told you that you had an STD since your first study visit. Which one(s)? Check all that apply:

- a. Gonorrhea
- b. Chlamydia
- c. Syphilis
- d. Other

[*If SD-2* = *Other*:] SD-3 Other Specify (Text field)

## SEXUAL BEHAVIOR

The next couple questions will help us set up the rest of the questions in this section.

SU-1 Are you male, female or transgender?

Male

Female

Transgender Male to Female

Transgender Female to Male

SU-2 Since your first study visit on [*insert date*], have you had sex with males, females, or both males and females? Sex includes any oral, anal or vaginal sex.

Males only

Females only

Both Males and Females

Have not had sex in the last year.

We will now ask you some questions about sexual experiences you've had since your first study visit. We only want to know about partners you had oral, anal or vaginal sex with since [insert date].

Some questions will ask specifically about your sex partners' HIV status and what you did with partners who were HIV positive, HIV negative, and partners whose HIV status you did not know. We know you can't always be sure of a partner's HIV status. Please try to answer the questions based on what you knew and what your partners told you or did not tell you about their HIV status.

We know that it may be difficult to answer some of these questions if one or more of your sex partners do not identify as male or female, or if they are transgender. Except where we ask

specifically about transgender partners, please include these sex partners in your responses to the questions about sex with either men or women, whichever you think is most appropriate.

We also know that how people refer to their genitals can be unique and personal. The following questions may use words that don't perfectly fit how you or your partners refer to your bodies. Please answer the questions about specific sex acts the best that you can.

If SU-1 = Male or Male-to-Female AND SX-1 = "Only men", ask only <u>Male Sex Partners of Men</u> questions.

*If SU*-1 = *Male or Male*-to-Female *AND SX*-1 = "Only women", ask only <u>Female Sex Partners</u> <u>of Men</u> questions.

If SU-1 = Male or Male-to-Female AND SX-1 = "Both men and women", ask <u>Female Sex Partners of Men</u> questions first, followed by <u>Male Sex Partner</u> questions.

If SU-1 = Female or Female-to-Male AND SX-1 = "Only men" or "Both men and women", ask Male Sex Partners of Women questions.

If SX-1 = "Nobody" OR SU-1 = Female or Female-to-Male and "Only women", skip all remaining sexual behaviour questions.

# **Female Sex Partners of Men**

I prefer not to answer

The next questions are about women you had vaginal or anal sex with since your first study visit on [insert date]. "Vaginal sex" means you put your penis in her vagina. "Anal sex" means you put your penis in her butt.

FX-1. Since your first study visit, with how many different women did you have vaginal or ar sex?	nal
Number of women (1 to N)	
I prefer not to answer	
FX-2. With how many of these [ <i>FX-1</i> ] women did you have vaginal or anal sex without using	g a
condom or not using it the whole time?	
Number of women (0 to N)	
I prefer not to answer	
Check to make sure $FX-1 \le FX-2$ . If not, then display "The number of women you has sex without using a condom or not using it the whole time cannot be more than the number of women you had vaginal or anal sex with in the past 3 months. Please careful re-enter your response.", and loop back to enter the number.	
FX-3. Since your first study visit, how many of the [FX-2] women you had vaginal or anal se	X
without using a condom were:	
HIV positive? Number of women (0 to N)	
HIV negative? Number of women (0 to N)	
Women whose HIV status you did not know? (0 to N)	

Check to make sure that the numbers in FX-3 add up to the total N from FX-2. If not, then display "The number of HIV positive, HIV negative and HIV status unknown partners must add up to [FX-2]. Please carefully re-enter your responses.", and loop back to enter the numbers.

# **Male Sex Partners of Women**

The next questions are about men you had vaginal or anal sex with since your first study visit on [insert date]. "Vaginal sex" means he put his penis in your vagina. "Anal sex" means he put his penis in your butt.

FM-1. Since your first study visit, with how many different men did you have vaginal or anal sex?
Number of men (1 to N)
I prefer not to answer
FM-2. With how many of these [ <i>FM-1</i> ] women did you have vaginal or anal sex without using a condom or not using it the whole time?  Number of men (0 to N)  I prefer not to answer
Check to make sure $FM-1 \le FM-2$ . If not, then display "The number of men you had sex without using a condom or not using it the whole time cannot be more than the number of men you had vaginal or anal sex with in the past 3 months. Please carefully re-enter your response.", and loop back to enter the number.
FM-3. Since your first study visit, how many of these [FM-2] men you had vaginal or anal sex without using a condom were:  HIV positive? Number of men (0 to N)  HIV negative? Number of men (0 to N)  Men whose HIV status you did not know? (0 to N)  I prefer not to answer
Check to make sure that the numbers in FM-3 add up to the total N from FM-2. If not, then display "The number of HIV positive, HIV negative and HIV status unknown partners must add up to [FM-2]. Please carefully re-enter your responses.", and loop back to enter the numbers.
Male Sex Partners of Men
The next questions are about men you had sex with since your first study visit on [insert date].
"Oral sex" means you put your penis in his mouth, or he put his penis in your mouth. "Anal sex" means you put your penis in his butt, or he put his penis in your butt.
SX-1. Since your first study visit, with how many different men did you have oral or anal sex?  Number of men (1 to N)
I prefer not to answer

SX-2. Since your first study visit, with how many different men did you have anal sex?
SX-3. Since your first study visit, of the (SX-2) men you had anal sex with, with how many different men did you have anal sex without a condom?
SX-4. Since your first study visit, of the (SX-2) men you had anal sex with, how many were new partners, meaning guys you had never had anal sex with before [insert baseline visit date]?
The next few questions will ask about times you had sex with more than one man in the same encounter since your first study visit on [insert baseline visit date]. For these questions, a threesome involves sex with you and two other men. Group sex involves sex with you and at least 3 other men. When the question asks about the number of partners you had during a threesome or group sex, please write the total number of different partners you had across all encounters.
GS-1: Since your first visit, how many times did you have sex with more than one man in the same encounter? (Threesome or group sex)  Number of events (times you had sex with more than one man in the same encounter)  I prefer not to answer
[ <i>If GS-1</i> > 0:] GS-2: Since your first visit, how many times did you have sex with only two other men in the same encounter (a threesome)?  Number of events (times you had a threesome) (0 to GS-1) I prefer not to answer
[ <i>If GS-2</i> > 0:] GS-3: Since your first visit, in these [ <i>GS-2</i> ] threesomes, with how many different men did you have anal sex?  Total number of men with whom you had anal sex during a threesome (0 to SX-2) I prefer not to answer
[ <i>If GS-3</i> > 0:] GS-4: Since your first visit, of the [ <i>GS-3</i> ] men you had anal sex with during threesomes, with how many different men did you have anal sex without a condom?  Total number of men with whom you had anal sex without a condom (0 to SX-3) I prefer not to answer
[ <i>If GS-4</i> > 0:] GS-5: Of the [ <i>GS-4</i> ] men with whom you had anal sex without condoms during threesomes, how many were:  HIV-Positive HIV-Negative

Didn't know his/their HIV status
[ <i>If GS-1</i> > 0 & <i>GS-2</i> < <i>GS-1</i> :] GS-6: Since your first visit, how many times did you have sex with 3 or more other men in the same encounter (group sex)?  Number of events (times you had sex with three or more other men) (0 to GS-1) I prefer not to answer
[ <i>If GS-6</i> > 0:] GS-7: Since your first visit, in these [ <i>GS-6</i> ] times you had group sex (sex with 3 or more other men), with how many different men did you have anal sex?  Total number of men with whom you had anal sex during group sex (0 to SX-2) I prefer not to answer
[ <i>If GS-7</i> > 0:] GS-8: Since your first visit, of the [ <i>GS-7</i> ] men you had anal sex with during group sex, with how many different men did you have anal sex without a condom?  Total number of men with whom you had anal sex without a condom (0 to SX-3)  I prefer not to answer
[ <i>If GS-8</i> > 0:] GS-9: Of the [ <i>GS-8</i> ] men with whom you had anal sex without condoms during group sex, how many were:  HIV-Positive HIV-Negative Didn't know his/their HIV status
In the next section we will ask you more about the [SX-2] men you had anal sex with.
Ongoing Partners In this section, we will ask you about what you have done with the [1-3] partners that you provided details about in your first study visit. You nicknamed these partners [insert initials for partners 1-3].
For Each Partner: SX-5 Do you remember who you nicknamed [insert partner initials]? Yes No
If $SX-5 = Yes$ , continue with questions for that partner. If $SX-5 = No$ , skip partner-specific questions for this partner and start at $SX-5$ for next ongoing partner.
SX-6 Have you had anal sex with [insert partner initials] since your first study visit on [insert date]?  Yes No
[ <i>If SX-6</i> = <i>Yes:</i> ] SX-7 Since your first study visit, how many times did you and [ <i>insert partner initials</i> ] have anal sex?

Number of times (0 to N)
SX-8 Since your first study visit, how many times did you and [insert partner initials] have anal sex without using a condom or not using it the whole time?  Number of times (0 to N)
SX-9 Since your first study visit, when you and [insert partner initials] had anal sex without a condom were you the top (your penis in his butt), bottom (his penis in your butt) or both? Check only one.  Both top and bottom  Top only  Bottom only
SX-10 Since your first study visit, during the time you were having sex with [insert partner initials], did [insert partner initials] have sex with anyone else?  Yes  No  Don't know
The next few questions will ask about times you and [partner initials] had sex with at least one other man together in the same encounter. For these questions, a threesome involves sex with you, [partner initials], and one other man (a total of 3 men). Group sex involves sex with you, [partner initials], and at least 2 other men (a total of 4 or more men). When the question asks about the number of partners you had during a threesome or group sex, please write the total number of different partners you had across all encounters.
SX-11 Since your first study visit, did you and [insert partner initials] ever have sex with other people in the same encounter? (Threesome or group sex)  Yes  No  Don't know
[ <i>If SX-11</i> = " <i>Yes</i> ":] GS-10: In the past 3 months how many times did you and [ <i>partner initials</i> ] have sex with only one other man in the same encounter (threesome)?  Number of times (encounters involving sex with [ <i>partner initials</i> ] and 1 other man)
[ <i>If GS=10 &gt; 0</i> :] GS-11: Think of the most recent time you had a threesome with [ <i>partner initials</i> ].  Did anyone have anal sex during this threesome?  Yes No
[If GS-11=Yes] GS-12 Did anyone have anal sex without a condom during this threesome?  Yes  No

[If GS-12 =Yes] GS-13 Who had anal sex without a condom with each other in this threesome? Mark all that apply.  I had anal sex without a condom with [partner initials]  I had anal sex without a condom with the 3 <sup>rd</sup> partner  [Partner initials] had anal sex without a condom with the 3 <sup>rd</sup> partner.
GS-14 What was the HIV status of the 3 <sup>rd</sup> Partner? HIV-Positive HIV-Negative Didn't know his HIV status
[ <i>If SX-11</i> = " <i>Yes</i> ":] GS-15: In the past 3 months how many times did you and [ <i>partner initials</i> ] have sex with 2 or more other men in the same encounter (group sex)?  Number of times (encounters involving sex with you, [ <i>partner initials</i> ] and 2+ other men)
[ <i>If GS-15</i> > 0:] GS-16: Think of the most recent time you had group sex with [ <i>partner initials</i> ] and at least two other men. How many men took part in this group sex encounter? Include [ <i>partner initials</i> ], but not yourself.  Total number of men your last group sex encounter with [ <i>partner initials</i> ]
[ <i>If GS-16</i> > 0:] GS-17: Of these [ <i>GS-16</i> ] men involved in the last time you had group sex with [ <i>partner initials</i> ], how many were:  HIV-Positive HIV-Negative Didn't know their HIV status

[*If GS-16* > 0. *Create table with columns for each partner mentioned in GS-16*.] GS-18: In the table below, please mark which pairs of guys had anal sex without a condom during your most recent group sex encounter that included [*partner initials*].

	Partner initials	3rd	4 <sup>th</sup>	<i>Up to GS-16+1</i>
	initiais			GS-10+1
You				
Partner initials				
$3^{\mathrm{rd}}$				
4 <sup>th</sup>				
Up to GS-16 + 1				

[For all partners:]

SX-12 Have you told [insert partner initials] about your HIV test results?

Yes

No

SX-13 Has [*insert partner initials*] gotten tested for HIV since you first tested positive? He already knew he was positive

Yes, he tested for HIV No, he hasn't tested for HIV I don't know

[*If SX-13* = *Yes*:] SX-14 What was [*insert partner initials*]' HIV test result?

**Positive** 

Negative

Don't know

If SX-12=Yes and SX-13=Negative or Don't Know:] SX-15 To the best of your knowledge, is [insert partner initials] currently taking medicine to prevent himself from getting HIV? This might also be known as Pre-Exposure Prophylaxis or PrEP.

Yes

No

I don't know

*Repeat SX-5 to SX-14 for Ongoing Partners 2 and 3.* 

## **New Partners**

If SX-4 = 1 ask Partner 1 questions

If SX-4 = 2 ask Partner 1 and Partner 2 questions

If SX-4 = 3 ask Partner 1, Partner 2 and Partner 3 questions

*If*  $SX-4 \ge 4$  *ask* Partner 1, Partner 2, Partner 3 and Questions for  $\ge 4$  partners

Now, we'd like to ask you about partners that you had anal sex with for the first time after your first study visit on [*insert date*]. We'll call these your 'new partners'.

SX-16 Please enter a nickname or initials for the [insert number from SX-4 if < 3, or insert 3] most recent new anal sex partners.

We do not want to know the names of your partners. Please choose a nickname or initials that you will remember and that will best help you identify that person.

Display options below based on number from SX-4

a.	Partner 1 _	
b.	Partner 2 _	
c.	Partner 3	

SX-17 Did you have sex with [*insert partner initials*] once, or more than once since your first study visit?

Once

More than once

### For Each Partner:

SX-18 Which of the following statements about [*insert partner initials*]'s age is most true? He is more than 10 years younger than I am

He is 2-10 years younger than I am

He is within a year of my age

He is 2-10 years older than I am

He is more than 10 years older than I am

Don't know

## SX-19 Is [insert partner initials] Hispanic?

Yes

Nο

Don't know

SX-20 What is [insert partner initials]'s race? Check all that apply.

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Don't know

SX-21 Is/was [*insert partner initials*] someone that you feel or felt committed to (someone you might call your boyfriend, significant other, life partner, or husband)?

Yes

No

Don't know

SX-22 If you had to further describe the type of sex partner [*insert partner initials*] is/was, which of the following would you choose? Someone who ...

is a primary sexual partner

you have sex with on a regular basis, <i>but who is not a main or primary partner</i> you have had sexual contact with more than once, <i>but not on a regular basis</i>, and who you normally socialize with

you have had sexual contact with more than once, <i>but not on a regular basis</i>, and who you don't socialize with

you had sexual contact with only 1 time, but could find again if necessary you had never met before you had had sexual contact and never plan to see again you gave sex to for money or other goods or someone who gave you sex for money or other goods

SX-23 Where did you first meet [insert partner initials]?

Through friends

School or work

Online

Phone app

Circuit party or Rave

At church

Through a personal ad in a newspaper

On a telephone chat line or dating line Bar/Club Cruising area On the street Adult bookstore Bath house Sex club Sex resort Private sex party Sports club or gym Vacation or cruise Social organization Other SX-24 Did you share your HIV status with [insert partner initials] before you first had sex? Yes No Don't know SX-25 Did [insert partner initials] share his HIV status with you before you first had sex? Yes No Don't know [If SX-25 = Yes:] SX-26 What was [insert partner initials]'s HIV status at that time? HIV-negative **HIV-positive** [*If SX-*26 ≠ *HIV-positive*:] SX-27 To the best of your knowledge, what is [*insert partner* 

Don't know

For HIV-negative partners:

initials]'s HIV status today?
HIV-negative
HIV-positive

SX-28 To the best of your knowledge, is [*insert partner initials*] currently taking medicine to prevent himself from getting HIV? This might also be known as Pre-Exposure Prophylaxis or PrEP.

Yes

No

I don't know

For HIV-positive partners: SX-29 To the best of your knowledge, is [insert partner initials] currently taking medicines fo HIV?
Yes No I don't know
SX-30 To the best of your knowledge, does [insert partner initials] have an undetectable viral load?
Yes No I don't know
For all partners: SX-31 Since your first study visit on [insert date], how many times did you and [insert partner initials] have anal sex? Number of times (0 to N)
SX-32 Since your first study visit on [insert date], how many times did you and [insert partner initials] have anal sex <b>without using a condom or not using it the whole time</b> ?  Number of times (0 to N)
SX-33 Since your first study visit on [insert date], when you and [insert partner initials] had anal sex without a condom were you the top (your penis in his butt), bottom (his penis in your butt) or both? Check only one.  Both top and bottom  Top only  Bottom only
The next few questions will ask about times you and [partner initials] had sex with at least one other man together in the same encounter. For these questions, a threesome involves sex with you, [partner initials], and one other man (a total of 3 men). Group sex involves sex with you, [partner initials], and at least 2 other men (a total of 4 or more men). When the question asks about the number of partners you had during a threesome or group sex, please write the total number of different partners you had across all encounters.
SX-34 Since your first study visit, did you and [insert partner initials] ever have sex with othe people in the same encounter? (Threesome or group sex)  Yes  No
Don't know
[ <i>If SX-34</i> = " <i>Yes</i> ":] GS-19: In the past 3 months how many times did you and [ <i>partner initials</i> have sex with only one other man in the same encounter (threesome)?  Number of times (encounters involving sex with [ <i>partner initials</i> ] and 1 other man

[If GS=19 > 0:] GS initials]. Did anyon Yes No					a threesome with [partner
[If GS-20=Yes] GS Yes No	3-21 Did an	iyone have	e anal sex v	without a co	ndom during this threesome?
[If GS-21 =Yes] GS-22 Who had anal sex without a condom with each other in this threesome? Mark all that apply.  I had anal sex without a condom with [partner initials]  I had anal sex without a condom with the 3 <sup>rd</sup> partner  [Partner initials] had anal sex without a condom with the 3 <sup>rd</sup> partner.					
GS-23 What was the HIV-Positiv HIV-Negati Didn't know	ve ve		3 <sup>rd</sup> Partner?	•	
[ <i>If SX-34</i> = <i>Yes:</i> ] GS-24: In the past 3 months how many times did you and [ <i>partner initials</i> ] have sex with 2 or more other men in the same encounter (group sex)?  Number of times (encounters involving sex with you, [ <i>partner initials</i> ] and 2+ other men)					
and at least two oth [partner initials], b	er men. Ho ut not your	ow many r rself.	nen took p	art in this gr	group sex with [partner initials] roup sex encounter? Include r with [partner initials]
[partner initials], h HIV-Po HIV-N	ow many v ositive	vere:		olved in the l	ast time you had group sex with
[ <i>If GS-25</i> > 0. <i>Create table with columns for each partner mentioned in GS-25</i> .] GS-27: In the table below, please mark which pairs of guys had anal sex without a condom during your most recent group sex encounter that included [partner initials].					
	Partner initials	3rd	4 <sup>th</sup>	<i>Up to GS-25+1</i>	
You				33 23 1	
Partner initials					
3 <sup>rd</sup>					
4 <sup>th</sup>					

Up to GS-25 + 1

Thank you for telling us about [Partner X]. Next, we'd like to ask you about [Partner X+1].

Partner 1 section replicated for partners 2 and 3, but excluded here for brevity.

# **Questions for ≥ (Named Ongoing and New Partners) male sex partners**

The next questions are about any other partners that you haven't answered questions about yet. This should be the [(SX-2) - (Named ongoing partners + new partners)] men you had anal sex with since your first study visit on [insert date] other than [insert nicknames from SX-4 and Ongoing Partners]. These could be partners that you had anal sex with before your first study visit and continued having sex with after OR new partners that you first had anal sex with after your first study visit. The questions will cover all of these partners as a group.

you have	With how many of these [(SX-2) – (Named Ongoing partners + New partners] men did e anal sex <b>without using a condom or not using it the whole time</b> ?  Number of men (0 to N)
n to	Check to make sure $\leq$ (SX-2) – (Named Ongoing + New). If not, then display "The number of other men you had anal sex without using a condom cannot be more than the otal number of men you had anal sex with in the past 3 months. Please carefully re-enter your response.", and loop back to enter the number.
using a c	In the past 3 months, how many of these [ <i>SX-31</i> ] men that you had anal sex without condom were:  HIV positive? Number of men (0 to N)
	IIV negative? Number of men (0 to N)
	Men whose HIV status you did not know? Number of men (0 to N)
(	Shack to make sure that the numbers in SY 32 add up to the total N from SY 31. If not

Check to make sure that the numbers in SX-32 add up to the total N from SX-31. If not, then display "The number of HIV positive, HIV negative and HIV status unknown partners must add up to [SX-31]. Please carefully re-enter your responses.", and loop back to enter the numbers.