

**Identification of behavioral and clinical predictors of early HIV
infection
(Project DETECT)**

Attachment 9a

Phase 2 HIV Symptom and Care Survey (English)

Public reporting burden of this collection of information is estimated to average 5 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.

**Project DETECT: Part 3 Questionnaire #1
HIV Symptom and Care Survey**

Description: REDCap Survey for study staff to complete with participants in Part 3/Phase 2 (Symptom and Care) at each follow-up visit. Study staff will complete a set of ‘Face page’ questions, the participant will be asked about providing consent and, for those who provide consent, the study staff will ask them the remainder of the survey questions and enter their answers into the computer.

FACE PAGE

Note to study RA: Input the dates and study ID number(s).

FP-1 Research assistant ID: _____

FP-2 UW Study ID for part 2: _____

FP-3 UW Study ID for part 3: _____

FP-5 Visit Date: MM/DD/YYYY

Note for study staff: If this is the participant’s first Part 3 visit (Visit #1) the previous visit date should be the participant’s Part 2 visit date.

FP-6 Previous Visit Date: MM/DD/YYYY

FP-7 Visit number: _____

RESEARCH STAFF HANDS COMPUTER TO PARTICIPANT

CONSENT

[Show section if FP-7 = 1.]

We've already discussed the following question with you but would like to document your answer electronically. If you have any questions about what we're asking, please talk to the study staff before responding.

CT-1 Do you agree to take part in the study?

Yes

No

We are asking you to agree to freeze part of your blood and oral fluid specimens at the CDC for future use. We may use these samples for research in the future. Nothing that could be linked to you will be kept with your blood or oral fluid specimens. We are not sure what studies might be done in the future. They might include standard tests as done at hospitals, tests for HIV or other viruses or on your immune system (ability to fight infection). We will not test for genetic problems or use the blood or oral fluid specimens for cloning or commercial purposes.

CT-2 Do you agree to storage of your specimens for future use?

Yes, I give consent for my blood and oral fluid specimens to be stored at CDC for the future use as outlined above.

No, I DO NOT give consent for my blood and oral fluid specimens to be stored at CDC for future research.

If CT-1 or CT-2 = "No," participant has declined participation in the study. Screen will say, "Please pause the survey here and talk to study staff." Study staff will discuss the response with the participant and address any questions or concerns. If participant does not want to participate, study staff will end the survey and withdraw participant from the study. If participant does want to participate and responded inaccurately for any reason, study staff will help the participant navigate back to the question and answer it correctly, so the participant can proceed with the remainder of the survey.

The survey will start once you click the "Next question" button.

PRIOR STUDY PARTICIPATION

[Show section if FP-7 = 1.]

PS-1. Have you previously participated in an HIV vaccine trial?

Yes

No

I don't know

[If PS-1 = "Yes"] **PS-2.** Which did you receive as part of your study participation?

A vaccine

A placebo

I don't know/I never learned which one I received

SYMPTOMS

SY-1 Since your last visit on [*insert date*], have you had any of these symptoms? Check all that apply.

- a. Sore throat
- b. Fever and/or chills
- c. Nausea
- d. Vomiting
- e. Diarrhea
- f. Headache(s)
- g. Fatigue
- h. Soreness or pain in your joints or muscles
- i. Swollen or sore lymph nodes
- j. Body Rash
- k. Sores, bumps, or rashes on your genitals
- l. Changes in hearing or vision
- m. Rash on the palms of your hands or on the soles of your feet
- n. Abdominal pain
- o. I haven't experienced any of these symptoms since my last visit

For any checked symptoms:

SY-2a-SY-2n You said that you have had [*insert symptom*] since your last visit on [*insert last visit date*]. Do you have [*insert symptom*] today?

- Yes
No

SY-3a-SY-3n When did you first experience this symptom [*insert symptom*]? Please enter a day, month, and year in MM/DD/YYYY format. If you cannot remember the exact day, please just enter the month and the year.

MM/DD/YYYY

[*If SY-2a-SY-2j = No:*] SY-4a-SY-4n When did you last experience this symptom [*insert symptom*]? Please enter a day, month, and year in MM/DD/YYYY format. If you cannot remember the exact day, please just enter the month and year.

MM/DD/YYYY

If reported any symptoms:

SY-5 Did you go to a doctor or health care provider because of your symptom(s)?

- Yes
No

SY-6 Did you miss work or school because of your symptom(s)?

- Yes
No
Don't know

SY-7 Were you hospitalized because of your symptom(s)?

Yes

No

HIV CARE

HC-1 Do you currently have a doctor or medical provider for HIV care?

Yes

No

HC-2 Since your last visit on [*insert date*], have you been to a doctor or medical provider for HIV care?

Yes

No

[*If HC-2 = "Yes"*] HC-3 When did you last see your HIV doctor or medical provider? Please enter a day, month, and year in MM/DD/YYYY format. If you cannot remember the day, please just enter the month and year.

MM/DD/YYYY

HC-4 Are you currently taking medicines to treat your HIV?

Yes

No

[*If HC-4 = No:*] HC-5 Have you taken medicines to treat your HIV since your last visit on [*insert date*]?

Yes

No

[*If HC-4 = Yes OR HC-5 = Yes:*] HC-6 When did you start taking medicines to treat your HIV? Please enter a day, month, and year in MM/DD/YYYY format. If you cannot remember the day, please just enter the month and year.

MM/DD/YYYY

[*If HC-4 = No AND HC-5 = Yes:*] HC-7 When did you stop taking medicines to treat your HIV? Please enter a day, month, and year in MM/DD/YYYY format. If you cannot remember the day, please just enter the month and year.

MM/DD/YYYY

This is the end of the survey.