

Form Approved
OMB No. 0920-1402
Expiration Date: XX/XX/XXXX

**Surveillance of HIV-related service barriers among Individuals with Early or
Late HIV Diagnoses (SHIELD)**

Attachment 5C

Model Qualitative Interview Consent (English)

New

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 (0920-1402)

Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD)

Model Consent for Qualitative In-Depth Interviews

*****Model Consent Form*****

Statement of Informed Consent

[Interviewer Note: The following statement must be read to all potential participants]:

You were chosen for this interview because of your recent lived experiences related to HIV testing and diagnosis. Taking part in this interview is up to you. You can choose to participate or not to participate. You do not have to take part in the interview if you do not want to. If you decide to take part, you may leave the interview at any time. There are no penalties if you choose not to take part or to leave the interview early. If you are currently incarcerated, taking part in this interview will not affect your parole or release.

Why we are doing this project

HIV is the virus that causes AIDS. Your health department and the Centers for Disease Control and Prevention (CDC) are doing this project to learn more about people living with HIV, including the services they use and need. We intend to use this information to help improve programs that keep people healthy and get them the help they need.

What we will need from you

If you choose to take part in this interview, I will ask you some personal questions.

Answering the questions will take about 90 minutes. You do not have to answer any question you do not want to answer.

The questions ask about your:

- Health and experiences with healthcare
- Experiences with HIV testing and PrEP
- Communication with sex partners and sex practices

We send the answers to CDC, but we don't send them your name. Instead, we will assign a code number to your answers. We do not send CDC any information that identifies you or could be traced back to you. Your answers are confidential. All project materials are kept in a locked cabinet or secure computer.

The interview will be audio-recorded and transcribed. The audio-recording will take place over the phone and recorded in a transcript. All identifying information such as names of people, schools, places of employment will be removed from transcripts. Audio-recordings collected during the interview will be destroyed by the end of the project period. A small number of interviews may be observed by supervisors to provide feedback to project staff on their work.

What you can expect from us

Privacy

We protect your privacy. All information you give us will be private and confidential. Your records will be confidential as much as the law allows. Your answers will be grouped together with answers from other participants so that no one will know which answers are yours. We will send information from this project to CDC, but we will not send any information that could identify you. Federal law protects the confidentiality of information kept at CDC.

Token of appreciation

You will receive a token of appreciation in the amount of \$50 for taking part in the interview. If you choose to leave the interview early, you may keep the token of appreciation.

Things to consider

- There is no cost to you (other than your time and effort) for taking part in this interview.
- If you like, we can give you information about how to avoid giving HIV to someone else.
- If you like, we can give you information about where to get medical and social services.
- There are no direct benefits from taking part in this interview. However, the information you give us can help us improve services available to other people living with HIV.
- There are minimal risks from being a part of this project. Some of the questions may make you feel uncomfortable or may be too personal. Remember: You do not have to answer any questions you do not wish to answer.

Agreement**Do you have any questions?**

[Interviewer Note: Answer the participant's questions about the interview before proceeding to the next section.]

If you have any additional questions about this project or the token of appreciation, you can ask me and I will do my best to answer. If there is a question I am not able to answer, you can directly contact the person you talked to at the health department about this survey, using the contact information they gave you. If you no longer have this contact information, you can reach your health department at

[Programming note: project-area specific information]

(phone number provided by health department)

If you have any questions about your rights and how the project works across the country, please contact

- (If applicable) The institutional review board (IRB) at (State/Local Health Department) at (phone number).
- (If applicable) (Local IRB contact) at (phone number).

Now I will read you a consent statement and you can choose to provide your consent or not to consent to the interview:

I agree to take part in the project described here. I have been read the statement, understand the statement, and all my questions have been answered, or I have been given contact information to get my questions answered by others. I understand that my participation is completely voluntary. By saying yes, I agree to participate in the interview.

Optional Follow-up Survey and Data Linkage

Thank you for agreeing to participate in this interview! At the end of this interview, you will be offered the option to complete a separate 50-minute survey about some of the topics discussed in this interview.

- A separate token of appreciation will be offered for taking part in the survey.
- If you agree to participate in the survey, we will connect your interview responses with your survey answers using the ID number assigned to you for this project. Your name and other identifying information will not be stored or shared.
 - o If you like to participate in the voluntary follow-up survey and do not remember your survey ID, please reach out to me so that I can give it to you.
- There is no penalty for not participating in the follow-up survey. You can complete this interview and receive your token of appreciation at any time.

QUALCONSEN Do you agree to take part in the interview?

T

No	0
Yes	1

Skip Pattern	If Respondent does not consent (CN1 = 0['No']), this survey will STOP immediately. GO TO END.1 to thank participant for their time and offer any referrals. Else, GO to INTRO.NOTE
---------------------	--

AFFIRM Interviewer initials to confirm affirmative consent
[Interviewer note: add initials and date below]
[XX] [Date]

AUDCONSENT Do you agree to the use of audio recording for this interview?

No	0
Yes	1

AUDAFFIRM Interviewer initials to confirm affirmative consent to audio recording
[Interviewer note: add initials and date below]
[XX] [Date]

INTSIGN

I have fully explained to the participant the nature and purpose of the procedures described above and the risks involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

[Interviewer note: add initials and date below]
[XX] [Date]

Quantitative Survey Option	If the respondent completes consent for the qualitative interview (CN=1['Yes']), then proceed to the in-depth interview guide. At the end of the interview, let the participant know that they are eligible to complete another survey.
-----------------------------------	---

QUANTCONSENT Do you agree to take part in a follow-up survey?

No	0
Yes	1

Skip Pattern	If Respondent does not consent (QUANTCONSENT = 0['No']), the qualitative interview will STOP immediately. GO TO END.1 to thank participant for their time and offer any referrals. Else, GO to INTRO.NOTE
---------------------	---

LINKAGE	Do you agree to have your interview and survey responses connected?	
	No	0
	Yes	1

Skip Pattern	If Respondent does not consent to data linkage (LINKAGE = 0['No']), the qualitative interview will STOP immediately. GO TO END.1 to thank participant for their time, let them know that they will not be eligible to complete the survey, and offer any referrals. Else, GO to INTRO.NOTE
---------------------	--

QUANTAFFIRM Interviewer initials to confirm affirmative consent for quantitative survey

[Interviewer note: add initials and date below]

[XX] [Date]

End of Qualitative Interview	GO TO END.1 to thank participant for their time and offer any referrals. Else, GO to INTRO.NOTE
-------------------------------------	--