Form Approved OMB No. 0920-1027 Expiration Date: 08/31/2017

Title of Project: Formative Study to Inform HIV Screening and PrEP Resources for Health Care
Providers

#### Attachment B: Consent and Moderator's Guide

Public reporting burden of this collection of information is estimated to average 75 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 (0920-1027)

#### **PART A: Consent**

# **Introduction and Purpose:**

You have been asked to take part in a study. The purpose of the study is to conduct individual interviews to learn about your views related to a communications campaign. What we learn from this study will be used to develop materials for health care providers about HIV screening and pre-exposure prophylaxis (PrEP). RTI International, a non-profit company in North Carolina, is conducting the interview. The interview is sponsored by the Centers for Disease Control and Prevention (CDC).

#### **Procedures:**

During the interview, we will ask you to review some draft materials and tell us your thoughts. The interview, including the consent process and a short survey, will take about 1 hour and 15 minutes. We will be doing interviews with health care providers in Atlanta, GA, Houston, TX, and Philadelphia, PA. About 36 health care providers will take part in the interviews.

CDC staff working on this project may observe the interview through a one-way mirror, by phone, or by live video-stream from a computer at another location. There are also note takers taking notes behind a one-way mirror.

Before the interview, you will be asked to fill out an electronic survey on a laptop or tablet. Your name will not go on this survey. The survey will contain some general questions about your practice and your patient population.

# **Benefits:**

There is no direct benefit to you for being in this interview. However, you will be exposed to educational materials that are designed to serve as resources to share with patients and for the provider to use in their day to day practice. You may find the discussion interesting and informative. What we learn from the interview will help us to improve the materials being developed.

# **Risks:**

The questions we ask are not meant to be sensitive. Still, there is a chance that you may feel discomfort about some of the questions we ask. During both the interview and electronic survey, you may choose not to answer any question you wish or end your participation at any time. We do not know of any other risks related to taking part in this study.

# **Privacy:**

Your responses will be kept secure. We will be audio recording the interview. Digital files from audio recordings will be kept on a password-protected computer, accessible only by authorized staff. Notes will be made of the audio recordings. We will only refer to people by their first name in the notes. Because we are not transcribing the audio recordings, we will keep the records for reference if needed to confirm the notes. All audio files will be destroyed three years after completion of the project. Your comments will be kept private to the extent allowable by law. The notes will also be kept on a password-protected computer. Only authorized project staff will be able to see them. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. These forms will be destroyed after the interview ends. However, there is still a small risk that your privacy could be broken.

Also, any information that this local facility already has about you -- because you have been in other projects -- will still be kept there. You may be contacted by them to be in other projects in the future. If you have not been contacted by this facility before this project, they will not keep any of your contact information without your permission.

#### **Reimbursement:**

We will give you \$250 as a token of appreciation for participating in this study.

# Right to Refuse or Withdraw:

It is your choice to take part in this interview. You can choose not to talk about any topic. You can end the interview at any time. You can withdraw from the study for any reason at any time.

# **Persons to Contact:**

If you have questions about the interview, you can call Dr. Jennifer Uhrig at 1-800-334-8571 extension 23311. She can be reached between 9 AM and 5 PM Eastern Standard Time Monday - Friday. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

# **Your Consent:**

YES, I agree to participate.	→ CONTINUE TO SURVEY
NO, I do not wish to participate.	→ TERMINATE

# **PART B: Electronic Survey: Information on Health Care Practice**

We recognize that many health care providers split their time between private practices (individual or group) and practices that are public or university based. For the following question, please provide responses for both these practice types as applicable to your own practice of medicine. Please use your best estimate.

	<u>Pr</u>	ivate Pı	<u>actice</u>	Public or University Based Practice
1.	Number of patients you see in a month.		_	
2.	Number of HIV-infected patients you see in a month.		_	
		Mal	<u>e</u>	<u>Female</u>
3.	What percent of all of your patients are male vs. female? (Please use your best estimate)		_	
4.	What racial/ethnic groups do you serve? (	RECO	RD <u>ALL</u> THA	T APPLY)
	Black/African American			
	American Indian/Alaska Native			
	Asian American/Pacific Islander			
	Hispanic/Latino			
	White/European American			
5.	Which of the following groups do you ser	ve? <b>(RI</b>	ECORD <u>ALL</u>	THAT APPLY):
	Uninsured			
	Underinsured			
	Women			
	Heterosexual Men			
	Men who have sex with men (MSM)			
	Transgender Men			
	Transgender Women			
	Injection Drug Users			

6.	Now I am going to ask you to describe your sexual identity. Would you describe yourself as [READ]:
	Homosexual or "gay"
	Bisexual
	Heterosexual or "straight"
	Other, specify
	Don't know
	Refused
	Which medical associations do you belong to? Please select one or more of the following ociations. [MARK ALL THAT APPLY]
	American Academy of Family Physicians (AAFP)
	American Academy of HIV Medicine (AAHIVM)
	American Academy of Physician Assistants (AAPA)
	American Association of Nurse Practitioners (AANP)
	American College of Physicians (ACP)
	American Congress of Obstetricians and Gynecologists (ACOG)
	American Medical Association (AMA)
	Gay and Lesbian Medical Association (GLMA)
	HIV Medicine Association (HIVMA)
	Infectious Diseases Society of America (IDSA)
	International AIDS Society (IAS)
	National Association of Hispanic Nurses
	National Black Nurses Association
	National Hispanic Medical Association (NHMA)
	National Medical Association (NMA)
	Other [Specify:]
	None of these
Pr	e-Exposure Prophylaxis (PrEP)
yea	als have shown that giving specific antiretrovirals daily to uninfected people for months to ars can reduce their risk of acquiring HIV infection through ongoing sexual or drug injection naviors. This method is called pre-exposure prophylaxis or PrEP.
Ple	ase tell us about your experience with PrEP.
	Yes No
8.	Have you ever heard of pre-exposure prophylaxis

(PrEP) before today?	
<b>9.</b> Have you read the 2014 CDC Clinical Guidelines for PrEP use?	
<b>10.</b> Do you discuss PrEP with the patients you see?	
<b>11.</b> Have you ever prescribed PrEP for any of the patients you see?	
<b>12.</b> Are you currently managing any patients on PrEP?	
<b>13</b> . Who do you think PrEP should be prescribed for? <i>Select all that apply.</i>	
Injection drug users	
Men who have sex with men (MSM)	
People with a sexually transmitted infection	
People who change sex partners frequently	
Uninfected partners with HIV-infected spouses/partners (serodiscordant couples)	
Uninfected partners in HIV-discordant couples during attempts to conceive	
Other [Specify:]	
No one	
<b>14.</b> What are some of the reasons why you have not prescribed PrEP? <i>Select all that apply.</i>	
I don't know enough about it	
I do not have experience prescribing antiretroviral medications	
No one has asked for it	
I do not routinely screen my patients for risky sexual behaviors	
I do not routinely screen my patients for drug-injecting behavior	
I don't think insurance will cover the cost	
Patients may have harmful side effects	
Patients may engage in riskier sexual behaviors	
Other [Specify:]	
None of these	

# **Information Needs**

. Would you be interested in receiving information about...

				<u>Yes</u>	<u>No</u>
<u>Topic</u>					
a. Reducing HIV transmission					
b. Conducting HIV screening					
c. Conducting other STD screen	ning				
d. Partner services					
e. Screening for risky sexual be	haviors				
f. Screening for risky alcohol ar	nd illicit dr	ug use behav	viors		
g. Helping patients modify risk	y sexual be	haviors			
h. Helping patients modify alco	hol and illi	icit drug use			
j. Helping patients initiate PrEP	•				
k. Managing a patient on PrEP					
l. Identifying candidates for PrE	EΡ				
m. Post-exposure prophylaxis (	PEP)				
Use of Electronic Media					
<b>16</b> . How often do you do the follow	ing for pro	ofessional pu	rposes?		
	<u>Daily</u>	<u>Weekly</u>	<u>Monthly</u>	Less than once per month	<u>Never</u>
<ul><li>a. Use an app on a portable device, such as an iPad or Smart phone</li></ul>					
b. Download content to a portable device, such as an iPad or Smart phone					
c. Access content online, such					

as a medical journal article					
d. Access Medical blogs, such as those available through Medscape or Sermo					
e. Medical education (digital, such as Medscape or Pri-Med)					
f. Use social media, like Twitter or Facebook					
g. Listen to podcasts					
h. [INSERT OTHER BEHAVIOR]					
Patient Resources  17. Do you refer your patients to the	following	resources			
				<u>Yes</u>	<u>No</u>
a. Your practice's website					
b. CDC's website					
c. Other governmental websites					
d. Other websites(specify)					
e. Other electronic resources (sp	ecify)				
f. Printed materials					
g. Other (specify)					
Continuing Medical Education (C	ME)/Conti	inuing Educ	cation (CE)		
<b>18</b> . How do you obtain CME or CE	credits?				
a. Attending conferences					
b. Through employer-provided i					
c. Dinner presentations by local	chapter of	a professiona	al association		

d. Attending meetings of a professional association		
e. Journal supplement education programs		
f. Through online courses		
g. Other (specify)	_	
19. How useful are CME/CE programs about HIV care, treatment and	l prevention?	
a. Never useful		
b. Rarely useful		
c. Somewhat useful		
d. Always useful		
<b>20.</b> Do you currently use CME/CE courses or programs as a source of following topics?	f information abou	t the
<u>Topic</u>	<u>Yes</u>	<u>No</u>
a. Reducing HIV transmission		
b. Conducting HIV screening		
c. Conducting other STD screening		
d. Partner services		
e. Screening for risky sexual behaviors		
f. Screening for risky alcohol and illicit drug use behaviors		
g. Helping patients modify risky sexual behaviors		
h. Helping patients modify alcohol and illicit drug use		
j. Helping patients initiate PrEP		
k. Managing a patient on PrEP		
l. Identifying candidates for PrEP		

	m. Post-exposure prophylaxis (PEP)				
	n. [INSERT OTHER BEHAVIOR]				
21	. Would you be interested in CME/CE courses or programs about the fo	ollowing top	ics?		
<u>T</u>	' <u>opic</u>	<u>Yes</u>	<u>No</u>		
	a. Reducing HIV transmission				
	b. Conducting HIV screening				
	c. Conducting other STD screening				
	d. Partner services				
	e. Screening for risky sexual behaviors				
	f. Screening for risky alcohol and illicit drug use behaviors				
	g. Helping patients modify risky sexual behaviors				
	h. Helping patients modify alcohol and illicit drug use				
	i. Determining whether a patient is appropriate for PrEP				
	j. Helping patients initiate PrEP				
	k. Managing a patient on PrEP				
	l. Identifying candidates for PrEP adherence				
	m. Post-exposure prophylaxis (PEP)				
	n. [INSERT OTHER BEHAVIOR]				
	<b>21A.</b> Of the CME/CE courses or programs that you are interested in, please indicate your top three choices:				
	1				
	2				
	3				

# **Communicating with Patients about Risk Behaviors**

22.	<b>2.</b> What challenges, if any, prevent you from having discussions regarding high-risk sexual or substance use behaviors with your patients? <b>[MARK ALL THAT APPLY]</b>		
	a. Lack of time		
	b. Cultural difference between you and your patient		
	c. Gender difference between you and your patient		
	d. Lack of trust/relationship with patient		
	e. Lack of skills or training in this area		
	f. Patients are uncomfortable discussing the subject		
	g. I am uncomfortable discussing the subject		
	h. Other (specify)		
	i. There are no challenges to such discussions that I can identify		

**END OF SURVEY** 

# **PART C: Interview**

#### I. Welcome

Thank you for coming here today. Your participation is very important. I'm \_\_\_\_\_ and I'm from RTI, a non-profit research organization. The Centers for Disease Control and Prevention (CDC) is sponsoring this study. The purpose of this interview is to inform the development of a campaign that will promote CDC's recommendations for incorporating routine HIV screening into the medical care of patients; ages 18 to 64 years. Therefore, we will be asking you questions about concepts, messages, and materials developed for providers about screening patients for HIV. In addition, I will also be asking you about a tool kit being developed for providers to present information about pre-exposure prophylaxis (PrEP) to patients. Your insights today are very important as they will help inform the development of the final materials for health care providers that will be used in the campaign. We really appreciate your time today. We will have about 1 hour for our discussion.

Before we begin, I want to review a few ground rules for our discussion.

- Your participation is voluntary and you have the right to withdraw from the study at any time. You may choose not to answer any questions that you do not wish to answer.
- You have probably noticed the microphones in the room. They are here because I am audio taping [if applicable: and we have a live video stream]. At the end of today's discussion, I have to write a report. I want to give you my full attention and not have to take a lot of notes.
- Behind me is a one-way mirror. Some of the people working on this project (including CDC staff, as applicable) may be observing this discussion so that they can hear your opinions directly from you. [If applicable] CDC staff are listening on the phone / watching via a live video stream. There are also note takers taking notes behind a one-way mirror.
- Your identity and anything you personally say here will remain private and secure. Your name, address, and phone number will not be given to anyone, and no one will contact you after this interview is over. Interview notes will be kept secure and separate from identifiable information.
- In addition, we'll be talking to many people and writing a summary report based on all our findings. When we write the report, we will look at the results of the interviews as a group, not individually. We will not refer to you by name in the report.
- The informed consent has contact information for the project director, in case you have questions about the study, and RTI's Office of Research Protection, in case you have questions about your rights as a participant.
- Most importantly, there are no right or wrong answers. We want to know your opinions
  and what you think about the materials we will be discussing. I do not work for the

people sponsoring this study and I did not develop any of these materials, so don't hold back on giving me your honest opinions.

> Do you have any questions before we begin?

# II. Warm-up

I would like to begin our discussion by confirming some information you provided on your screener.

- > first name
- > number of years in practice
- ➤ Type of practice (e.g., Private, clinic, etc.)

# III. General Questions about HSSC Exposure

**1.** In the past 12 months, have you seen or heard any campaign messages for health care professionals about routine HIV screening for patients ages 18 - 64?

IF YES, PROBE: In your own words, would you please summarize what you

remember from those campaign materials? (You can mention anything you would like, including the main ideas or even pictures

or graphics that you remember.)

**2.** Have you heard of CDC's *HIV Screening*. *Standard Care*. (*HSSC*) campaign, also known as *HSSC*?

IF YES, PROBE: Do you use any *HSSC* materials in your office?

Do you recall how you obtained those materials (e.g. download,

conference, etc.)?

Have you shared *HSSC* materials with any of your colleagues?

Talked to colleagues (If yes, what did you talk about?)

Referred colleagues to the website?

As I mentioned previously, the campaign under development is focused on communicating CDC's HIV screening recommendations to health care providers.

# IV. Concept Testing

The goal of this next task is to determine which of several ways is best to present ideas and information about HIV screening to health care providers. To facilitate our discussion, I am going to show you several "creative concepts."

The concepts may be used in promotional materials such as advertising, brochures, pamphlets, etc., to convey an idea and to encourage you to take an action. Each one takes a slightly different approach for talking to you about screening patients for HIV. I would like you to focus on the general idea that is being communicated and not the specific wording or details of the design.

I am going to show you each concept one at a time. We'll discuss each one in turn and avoid comparing them until the end. So, after we discuss one, I will put it aside and ask that you think about the next one as if you didn't see the first one and so on.

Do you have any questions before we begin?

# [ROTATE ORDER OF CONCEPTS ACROSS INTERVIEWS. SHOW FIRST CONCEPT, ASK CLOSED-ENDED RECEPTIVITY ITEM, ASK OPEN-ENDED ITEMS, REPEAT PROCESS FOR ALL CONCEPTS.]

1. Overall, I like this concept.

- 2. What are your general impressions of this concept?
  - *OPTIONAL PROBE*: Do you like it? Not like it? What makes you say that?
- 3. What do you think of the design overall?

# OPTIONAL PROBES -

- Probe: Would this concept grab your attention? Why/why not?
- Probe: How do you feel about the images used in this concept? Are they helpful/engaging? Why/why not?
- Probe: How do you feel about the colors and graphics? What do you like/dislike about them?
- Probe: Are you able to see the headline and text easily? What do you think about the font/type?
- 4. What do you think of the content?

# OPTIONAL PROBES -

- Probe: Which words or phrases do you think are especially attention-getting or appealing?
- Probe: What, if any, words or phrases bother you? How should they be changed?
- Probe: What do you think about the headline?
- Probe: What do you think about the message?
- Probe: What do you think about the tagline?

- 5. What could be done to improve this concept?
  - *OPTIONAL PROBE*: Is there anything missing? Anything that needs to be added? Anything that should be deleted?

# [REPEAT FOR REMAINING CONCEPTS.]

# **Comparison of Concepts**

Lay both concepts out on the table and ask: If you had to choose one, which one of the concepts would most inspire or motivate you to screen all of your patients ages 18 - 64 for HIV? What made you choose that one?

# V. Message Testing

I am going to show you the first message CDC has developed for a new campaign to promote HIV screening. I am going to show you several sets of messages and ask you several questions about them. For now, let's avoid comparing the messages. Instead, let's consider each message on its own first.

# [ROTATE ORDER. SHOW FIRST MESSAGE, ASK CLOSED-ENDED ITEMS, ASK OPEN-ENDED ITEMS, REPEAT FOR ALL MESSAGES.

6. Overall, I like this message.

- 7. What are your general impressions of this message?
  - *OPTIONAL PROBE*: Do you like it? Not like it? What makes you say that?
- 8. What do you think about the content?

# OPTIONAL PROBES -

- Probe: What is the main idea that this message is trying to get across?
- Probe: How convincing or motivating is the message?
- Probe: Are there any parts of this message (i.e. words or phrases) that you find especially attention-getting or appealing?
- Probe: Are there any parts of this message (i.e. words or phrases) that bother you?

- 9. What could be done to improve this message?
  - *OPTIONAL PROBE*: Is there anything missing? Should anything be added or deleted?

# [REPEAT FOR REMAINING MESSAGES.]

# VI. Presentation of PrEP Kit

Next, I'd like to ask you about a tool for providers to present information about pre-exposure prophylaxis (PrEP) to patients.

The goal of this next task is to determine the most appropriate materials and resources for health care providers to utilize when presenting information about PrEP to patients.

# **General comments:**

I have for you a set of materials. Imagine you received this in the mail or picked it up at a conference. Please give it the same time and attention you would give it if we were not meeting today. However, be verbal when you look at the materials. Let me know what kinds of things you are thinking as you go through them.

# [GIVE PrEP KIT TO INTERVIEWEE. OBSERVE PROCESS OF REVIEW BY INTERVIEWEE.]

10. After seeing this kit, what are your thoughts about it?

# OPTIONAL PROBES -

- a. What do you think of the design overall?
  - Would this kit grab your attention? Why/why not?
  - How do you feel about the images used in this kit? Are they helpful/engaging? Why/why not?
  - How do you feel about the colors and graphics? What do you like/dislike about them?
  - What do you think about the font/type?
- b. What do you most like about this kit?
- c. What do you least like about this kit?
- d. What could be done to improve the kit?
- 11. Would you use this kit with your patients? If so, how / for what would you use this kit with your patients? If not, why not?
- 12. Do you like the current structure and format (i.e., hard copy)? Why/why not?
  - *OPTIONAL PROBE*: Would you prefer an electronic version (electronically via desktop, laptop, or tablet? mobile app?)
- 13. Are there other clinicians or staff in your practice that would potentially use or benefit from this? Who? How?
- 14. How would you prefer to access this kit (e.g., electronically via desktop, laptop, or tablet; mobile app; hard copy, etc.)?
- 15. How do you think most providers would like to access this kit?

# **Presentation of Materials:**

Next, I'd like to ask you about some of the individual materials in this kit. We'll discuss different types of materials – some are for providers and others are for patients. For each type of material, we'll be discussing two to three items.

# [INTERVIEWERS WILL ROTATE ORDER]

# General

16. What do you think is the point of this [insert material type]? How and when do you think you are supposed to use it?

- *OPTIONAL PROBE*: Who do you think is the intended audience for this [insert material type] (i.e., patient or provider)?
- 17. What do you think of the design overall?

# OPTIONAL PROBES -

- Probe: Would this [insert material type] grab your attention? Why/why not?
- Probe: How do you feel about the images used in this [insert material type]? Are they helpful/engaging? Why/why not?
- Probe: How do you feel about the colors and graphics? What do you like/dislike about them?
- Probe: Are you able to see the headline and text easily?
- Probe: What do you think about the font/type?

#### Content

- 18. What do you think about the title of this [insert material type]?
  - *OPTIONAL PROBE*: Is it appropriate? How could it be improved?
- 19. After reviewing the content of this [insert material type], what are your thoughts about it?

# OPTIONAL PROBES -

- Probe: Is there anything missing?
- Probe: Is there any other information that you feel should be added or removed?
- Probe: Is the information helpful?
- Probe: Which words or phrases do you think are especially attention-getting or appealing?
- Probe: Which words or phrases bother you? How could they be changed?
- Probe: Do you use something similar to this right now?
- 20. What do you most like about this [insert name or material type]?
- 21. What do you least like about this [insert name or material type]?

# Usability/Use

22. Does the organization or flow of information make sense to you? How could you improve the flow?

- 23. Does it provide enough guidance on how to use it?
- 24. How would you use this [insert name or material type] in your practice?
  - *OPTIONAL PROBE*: Where would you put it (e.g. in your office, mobile device, patient room, etc.)
- 25. Is this something that you would find useful for your staff? Other staff you work with?
  - *OPTIONAL PROBE*: How could it be improved to make it more useful for providers, such as yourself?

# **Improvement**

26. What could be done to improve this [insert material type]?

# OPTIONAL PROBES -

- Probe: Do you think there are any clinical studies or research findings that should be included in this [insert material type] that we have not included or that deserve more emphasis?
- Probe: Was the appropriate level of science referenced in [insert this material type] for providers?

# [REPEAT FOR REMAINING MATERIALS.]

# VII. Close

Okay, we are pretty much out of time. Do you have any last thoughts?

# [INTERVIEWER will check with observers for additional questions or comments.]

I would like to thank you for coming today and providing important feedback to CDC. This has been very useful in helping us to evaluate the different materials for promoting HIV screening as a routine part of care and a tool kit for providers to present information about pre-exposure prophylaxis (PrEP) to patients.