Form Approved OMB No. 0920-0775 Expiration Date 04/30/2011

ATTACHMENT 2a:

DATA COLLECTION INSTRUMENTS

Routine HIV Testing in Emergency Departments

Statement of burden for data collection instrument

Public reporting burden of this collection of information is estimated to average 1 hour 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: PRA (0920-0775)

ROUTINE HIV TESTING IN EMERGENCY DEPARTMENTS

Materials Testing

In-Depth Interview Guide

Objective and Task

Campaign Objective: To make HIV testing a routine part of care provided by emergency medicine physicians.

Task Purpose:

• To conduct materials testing to gain feedback on viability, appeal, and ability to persuade emergency medicine physicians to offer HIV testing as a routine part of care.

Data Collection

Setting: In-depth interviews (IDIs) will take up to 1 hour. A trained interviewer will meet with the participant. A note taker will take notes from behind the one-way mirror.

Consenting: Informed consent will be obtained at the beginning of the interview session.

Process: The interview will comprise the following steps:

- 1. Welcome:
 - a. **Welcome**—the interviewer will welcome the participant and explain the purpose of the discussion.
 - b. **Informed Consent**—the interviewer/ will briefly review the consent form and obtain the participant's informed consent.
 - c. **Warm-Up**—the interviewer will ask participant a few questions about their emergency department and their patients.
- 2. **Materials Testing. We will test the following campaign materials:** campaign folder with summary of the CDC HIV Testing Recommendations; campaign ad with scientific data points, call to action and graphic presentation; annotated recommendations; web site; three patient brochures; poster; two-sided resource sheet; and trifold business reply card.
- 3. **Close.** The interviewer/moderator will summarize the findings with the participant and ask for final thoughts.

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. I am conducting these interviews for the Centers for Disease Control and Prevention (CDC). The purpose of this interview is to get your feedback on materials that are being developed as part of a communication campaign for emergency medicine physicians.

Your insights are very important to us in this process, and your time today is appreciated. Our discussion will last about 1 hour.

[Interviewer gives participant consent form]

Here is an informed consent form. Take a moment to review it and if you agree to it, please sign it.

[Interviewer gives participant 5 minutes to review and sign consent form]

- The consent form states that you have agreed to be part of a study about HIV.
- Your participation is voluntary and you have the right to withdraw from the study at any time.
- You have probably noticed the microphones in the room. They are here because I am audio taping. 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 may be observing this discussion so that they can hear your opinions directly from you.
- Your identity and anything you personally say here will remain private. Your name, address, and phone number will not be given to anyone, and no one will contact you after this interview is over. When I write my report, I will not refer to you by name.
- 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 research 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

- 1. First, please tell me how you refer to the setting in which you practice medicine?
 - Emergency department
 - Emergency room
 - Acute care setting
 - Other?
- 2. Please tell me a little about you and the emergency department where you work.
 - Number of years in practice post-residency.

3. How about your patients? Can you tell me something about the patients you see in your department?

- Age
- Race
- Ethnicity
- Socioeconomic status

- HIV Status
- 4. What percentage of your patients have no other source of primary care?
- 5. Does the hospital where you work have standard operating procedures for testing patients for HIV?
 - [If Yes] How are those procedures set? (i.e. a medical board, the medical director)
- 6. What are some benefits of testing patients for HIV in the emergency department?
- 7. What are some challenges or barriers to testing patients for HIV in the emergency department?
- 8. Does the hospital where you work have standard operating procedures for counseling patients to be tested for HIV?
 - [If Yes] How are those procedures set? (i.e. a medical board, the medical director)
- 9. How many physicians work in the emergency department at your hospital, not including residents?
 - Residents?
 - Nurses?

III. Background and Campaign Description

Now, I'd like to give you a little background to help set the stage for our discussion today.

[Interviewer: Points to boards that provide a rationale for CDC's new recommendations, summarize the background for the new recommendations, and provide facts about women and HIV in the US.]

Rationale for CDC Recommendations

The CDC estimates that as of 2002, 38% to 44% of all persons in the United States had been tested for HIV, and that 16-22 million persons aged 18-64 years are tested for HIV annually. However, of the over one million persons living with HIV in the United States at the end of 2003, about one quarter (252,000 to 312,000 persons) are unaware of their infection and therefore do not benefit from clinical care to reduce morbidity and mortality. Some undoubtedly contribute unwittingly to continued transmission of HIV.

From 1994 to 1999, 43% of persons with AIDS first tested positive for HIV within 1 year of their AIDS diagnosis, compared with 51% of those diagnosed from 1990 to 1992. Late testers are more likely to be black or Hispanic, and to have been exposed through heterosexual contact; 87% had their first positive HIV test at an acute or referral medical care setting and 65% underwent HIV testing because of illness. Although many persons with HIV infection visit health care settings, including hospitals, acute care clinics, and sexually transmitted disease (STD) clinics in the years prior to their diagnosis, often they are not tested for HIV.

Interviewer: Points to board, summarizing the recommendations]

IV. Recommendations Summary

In an effort for more patients to know their HIV status, the CDC currently revised their recommendations on HIV screening and testing. These recommendations for human immunodeficiency virus (HIV) testing are intended for all health-care providers in the public and private sectors, including those working in

hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, community clinics, correctional health-care facilities, and primary care settings. The objectives of these recommendations are to increase HIV screening of patients, including pregnant women, in health-care settings; foster earlier detection of HIV infection; identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services; and further reduce perinatal transmission of HIV in the United States.

In health care settings:

- HIV screening is recommended in all health care settings, after notifying the patient that testing will be done unless the patient declines (opt-out screening);
- Persons at high risk for HIV infection should be screened for HIV at least annually;
- Separate written consent for HIV testing is not required. General consent for medical care is sufficient to encompass consent for HIV testing;
- Prevention counseling need not be conducted in conjunction with HIV testing.

Interviewer: Points to board, summarizing data]

While you may have comments on the recommendations, I would like to ask you to put those aside for the time being. The goal of our discussion today is hear your feedback about materials that are being developed for emergency medicine physicians about the new recommendations, not to debate the merits of routine HIV testing.

The information that you provide today will help the CDC to develop a communication campaign for emergency medicine physicians that will include scientific data to support the recommendations.

Do you have any questions before we begin?

V. Materials

The next few items I'm going to show you are tools for providers that are in the development stage.

Item 1: Campaign Folder

This is a folder that will be used to hold other reference materials, some of which we'll look at today.

- 1. What are your overall reactions to the outside of the folder **PROBE**: Color **PROBE**: Picture **PROBE**: Text
- What are your overall reactions to the inside copy of the folder and pocket?
 PROBE: Visual appeal and design
 PROBE: Size and shape
 PROBE: Content
- 3. How useful would something like this be in your department? How would you use it?

Item 2: Annotated Recommendations

This is a summary of CDC's new HIV testing guidelines I mentioned to you earlier. This summary will be included in the folder that we just discussed.

- What are your overall reactions to these annotated guidelines?
 PROBE: Visual appeal and design
 PROBE: Size and shape
 PROBE: Presentation
- 2. What do you think about the content?
- 3. How useful are the annotated guidelines as opposed to the full recommendations?
- 4. How useful would something like this be in your work? How would you use it?

5. How might this be changed to make it more relevant and/or useful for physicians who practice in hospital emergency departments?

Item 3: Campaign Ad (with scientific data points)

This is a journal advertisement that would appear in JAMA, Annals of Emergency Medicine or other medical journals, in an exhibitor program book or manual, or as a workshop announcement.

1. What are your overall reactions to the ad? **PROBE**: Visual appeal and design

PROBE: Size and shape **PROBE**: Presentation of the information

- 2. What do you think about the content?
- 3. What pieces of information do you pick up after looking at it briefly? **PROBE**: What do you think the ad is trying to tell you?
- If you were flipping through a medical journal, would your attention be drawn to this ad?
 PROBE: Would you pause to read/review it?
 PROBE: Would you remember it? Why/why not?
- 5. Would this ad prompt you to get more information on the Web or through the phone? Why/why not?
- 6. Would this ad cause you to consider testing all patients for HIV? Why/why not?
 PROBE: [If R says they are already testing their patients for HIV, ask, "Would this ad cause you to do anything differently in your department?"
 PROBE: Would you show this ad to a colleague?

Item 4: Patient Brochure 1

This item is written for patients. It is meant to be distributed to patients by physicians.

First, I'm going to ask you a few questions about how you currently use brochures with patients.

1. In your emergency department, how are brochures provided to patients?

PROBE: Do you actively give patients brochures when you think they need them? **PROBE**: How often do patients ask you for brochures? **PROBE**: How often do patients pick up brochures on their own? If so, where do they pick them up (waiting room)?

Give participant brochure #1

- 2. What are your overall reactions to this brochure? **PROBE**: Visual appeal and design **PROBE**: Size and Shape **PROBE**: Creditability
- What do you think about the content of the brochure?
 PROBE: How appropriate are the topics?
 PROBE: Is there anything missing?
 PROBE: Do you think the brochure is written at the right reading comprehension level for your patients?
- 4. What do you think about the title of the brochure?
- 5. Would you use this brochure as part of your patient education efforts? If yes, how would you use it? Would you put it in your waiting room? If not, why not?

Give participant brochure #2

- 1. What are your overall reactions to this brochure? **PROBE**: Visual appeal and design **PROBE**: Size and Shape **PROBE**: Creditability
- What do you think about the content of the brochure?
 PROBE: How appropriate are the topics?
 PROBE: Is there anything missing?
 PROBE: Do you think the brochure is written at the right reading comprehension level for your patients?
- 3. What do you think about the title of the brochure?
- 4. Would you use this brochure as part of your patient education efforts? If yes, how would you use it? Would you put it in your waiting room? If not, why not?

Item 6: Patient Brochure 3

Give participant brochure #3

- 1. What are your overall reactions to this brochure? **PROBE**: Visual appeal and design **PROBE**: Size and Shape **PROBE**: Creditability
- What do you think about the content of the brochure?
 PROBE: How appropriate are the topics?
 PROBE: Is there anything missing?
 PROBE: Do you think the brochure is written at the right reading comprehension level for your patients?
- 3. What do you think about the title of the brochure?
- 4. Would you use this brochure as part of your patient education efforts? If yes, how would you use it? Would you put it in your waiting room? If not, why not?

Item 7: Web Site

We are going to start our discussion by looking at a website that is being developed as part of the campaign. However before I put the website up on the screen, I would like to ask you about your use

of the CDC website. Interviewer shows the participants the cdc.gov web site on the wall projector screen.

1. How often do you visit the CDC website?

PROBE: What are some of the reasons you go to visit it? **PROBE**: Are there any other similar sites that you visit, such as NIH? How often?

Next, we are going to look at the campaign web site. I'm going to ask you to review some of the pages on the web site and provide your initial thoughts and reactions to them.

Home Page

We'll start with the web site's home page. Please take a moment to look it over.

[MODERATOR WILL POST THE WEB SITE HOME PAGE ON A SCREEN IN FRONT OF THE PARTICIPANTS.]

NOTE: IF A PARTICIPANT ASKS, THE SITE WILL BE 508 COMPLIANT BEFORE LAUNCH.]

2. What are your initial reactions to this webpage?

PROBE: Design- overall visual appeal and clarity **PROBE**: Amount of text/text size, colors and fonts **PROBE**: Graphics **PROBE**: Layout and organization

- 3. In your own words, what is the purpose of this webpage? **PROBE**: Is it relevant/important to you? **PROBE**: Who do you see this site as being direct towards?
- 4. What do you think about the content? **PROBE**: What parts would you use? **PROBE**: How would you use the information?
- 5. Is there anything that is not on this page that you think should be? What?
- 6. Where would you want to go next, after reviewing this page (i.e., page or link)? Why is that?

____Page / Link

7. Can you show me where you would need to click to get to the *Order Free Materials Page*? [MODERATOR WILL CLICK ON LINK TO THIS PAGE]

Order Free Materials Page

8. What are your thoughts about this page?

- PROBE: Is it clear how you would order materials?
- PROBE: Are the instructions easy to understand?
- PROBE: What do you think about how the materials are listed and categorized?

PROBE: Do you typically order patient materials yourself?

PROBE: Would you ask your staff or nurse to order materials from a website? Why or why not?

Calendar of events page [MODERATOR WILL CLICK ON LINK TO THIS PAGE]

9. What type of information did you think might be on this link?

PROBE: In your opinion, are these events relevant to the rest of the content of the web site?

PROBE: How likely is it that you would go to this subpage from the home page?

Resources page

[MODERATOR WILL CLICK ON LINK TO THIS PAGE]

10. This page list several resources for providers on HIV testing.

PROBE: How helpful would these materials be to you in your department?

PROBE: Which materials listed here would be the most useful? Why?

PROBE: How might you use these materials?

PROBE: Are there other materials that would be useful to include here? (i.e., posters, fact or information sheets?)

Frequently asked Questions and Answers [MODERATOR WILL CLICK ON LINK TO THIS PAGE]

The page contains frequently asked questions about the campaign.

11. What do you think of this page?

12. The FAQs cover a variety of different topics. Which of these are the most relevant to you?

13. Are there any that are missing?

14. In your opinion, what would be the most effective way to communicate the topic of each question to the user?

PROBE: What do you think about using a header key word above each question? A highlighted key word in the question itself? A mouse floater key word?

Useful Links Page

15. Next we are going to go to the *Useful Links Page*. But before we do, what links do you expect to see here?

[MODERATOR WILL CLICK ON LINK TO THIS PAGE]

16. How likely is it that you would click on this page from the home page?

17. Are there any you feel should be added to this list? Which ones?

18. Are there any that are you feel should be removed from this list?

19. How clear is it that you will be leaving the CDC site to get these links?

Item 8: Poster

- 1. Does your emergency department ever post posters from pharmaceutical companies, professional associations, a federal agency or other sources?
 - If so, what kind of posters do you have up in your emergency department now?
 - How is it decided what is posted?
- 2. Does your hospital have policies about what can be posted in the emergency department? If so, what are the policies? Are there some subject matters considered too sensitive to post? (e.g. STDs, HIV)

[Moderator shows poster]

This poster is being developed for emergency departments.

- 3. What were your initial reactions to this poster?
 - Visual appeal and design
 - Size and shape
 - Credibility

4. What do you think about the content of the poster?

- How appropriate is the topic?
- Is there anything missing? What?
- Thinking of the patients who are seen in your emergency department, what do you think about the reading comprehension level?
- What do you think of the title?

5. Would you put this poster up in your emergency department? If yes, where would you post it? If no, why not?

Item 9: Two-side Resource Sheet

CDC designed this to be a resource sheet, combining the names and addresses of organizations to assist you and your patients to learn more about HIV and HIV testing. Take a moment to look over the organizations.

- 1. Do you have anything like this now?
 - If so, is this better or worse and how so?
- 2. What are your general reactions to this?
- 3. Was there one organization in particular that you felt you could utilize?
- 4. Were there any organizations you thought were missing?

Item 10: Envelope Design

A typical physician will obviously receive a great deal of mail and therefore, he or she will often filter their mail, discarding some items without opening them.

- 1. How do you decide what to read and what to discard immediately?
- 2. Does someone filter your mail for you? Who?

[Moderator: SHOW envelope]

3. If you knew nothing about the project we discussed today and you received an envelope that looked like this, would you, in all honesty, open or discard the envelope?

- Why? Can you tell me a little more about that?
- [If discard] What would make you more likely to open it?

Item 11: Business Reply Card (BRC)

Many of the materials that we have discussed today will be freely available to emergency departments and providers like yourself. [SHOW Business Reply Card] This is an order form that would allow you to order the materials and have them mailed directly to you.

- 1. Is this something that you would use?
- Would you be more likely to use the card, call, email or use the website to order?Why do you say that?

3. Do you feel the descriptions given on the back side, center, gives adequate information of what the materials are about?

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 for working hard on this. Your feedback will be very useful in helping us to develop materials for promoting HIV testing as a routine part of care in the emergency department.