Form Approved
OMB No. 0920-0840
Expiration Date 01/31/2013

ATTACHMENT 3: CONSENT FORM AND AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

ASSESSING THE ACCURACY OF SELF-REPORTED HIV TESTING BEHAVIOR
HSC #__-___-____

INFORMED CONSENT TO JOIN A RESEARCH STUDY

You have been invited to join this research project because you responded to the sign at your health care provider's office. Your decision to take part is voluntary and you may refuse to take part, or choose to stop from taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you from your health care provider.

DESCRIPTION OF THE RESEARCH PROJECT

Your health department, together with the Centers for Disease Control and Prevention (CDC), is doing this project to learn more about how well people remember past HIV testing compared to their medical records. The purpose of this research is to compare what people remember about HIV tests with what is recorded in their lab reports and to identify whether differences exist in how well people remember receiving HIV tests.

This is a local study. The study will enroll about 900 people from the Houston area.

WHAT WE WILL NEED FROM YOU

If you choose to participate in the research study, you will be asked to complete a brief survey using a computer. The questions in the survey will ask if you have ever been tested for HIV and when. Completing the survey on the computer should take about 15 minutes. Completion of the survey is not part of your regular health care; however, the survey can be completed before or after your appointment. When you complete the survey, you will be asked to sign an authorization form. This form will allow your health care provider(s) to share your medical record with us.

After you complete the survey, your part of the research study will be finished. A member of the study team will visit the health care providers you identified in the survey to review your medical record. The information in your medical record will be used to compare with the information provided during the survey. This is how the study team will determine if differences exist in how well people remember receiving HIV tests.

WHAT TO EXPECT FROM US

Privacy

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We will protect your privacy. Your answers will be kept private in a locked file that only project staff can open. They will be identified through a special code number and only the investigator will know your name. Although we will send information to CDC, we will not send any information that could identify you or be traced back to you. Federal law protects the privacy of information kept at CDC. The privacy of your responses is assured under Section 308(d) of the Public Health Service Act. You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this project will be kept private as much as the law allows.

There is a separate authorization form that you will be asked to sign which explains the use and disclosure of your protected health information. This form will also allow us to contact your health care provider to review your medical record. These forms will be kept separate from your answers to the survey, but they will also be kept in a locked file that only project staff can open.

Payment
By participating in this study, you will not receive any additional services or treatment from either the study or your health care provider. If you answer the survey questions and agree to let us review your medical records, you will receive a $10 gift card as a token of appreciation.

OTHER THINGS TO CONSIDER

There will be no costs to you other than your time and effort as a result of taking part in this project.

You will receive no direct benefit from being in this study; however, your taking part may help patients get better care in the future. The answers you provide may help better inform health care providers about how many new infections of HIV occur each year and how well people remember being tested for HIV.

If you would like, we can give you information about how to prevent becoming infected with HIV or about where to get tested for HIV in Houston.

Some questions may make you feel uncomfortable. You do not have to answer any questions you do not wish to answer.

You may choose to end your participation in the study at any time. While completing the survey, you may choose to stop and inform the person who told you about the study and set up the computer for you. If you choose to stop after completing the survey, please contact the investigators at (832) 393-5080 to inform us of your decision.

QUESTIONS?

If you have any questions now or while you are completing the survey, please ask the person who explained the project to you today. If you have any questions about this project at a later time, please contact Dr. Karen Chronister, the principal investigator, at (832) 393-5080.

If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. You may also call the Committee if you wish to discuss problems, concerns, and questions; obtain information about the research; and offer input about current or past participation in a research study.

PARTICIPANT'S CONSENT

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I understand the information given to me about the research project and choose to take part in the project described. I understand my participation is completely voluntary and all my questions have been answered.

Printed Name of Participant	Printed Name of Individual Obtaining Consent
Signature of Participant	Signature of Individual Obtaining Consent
Date and Time	Date and Time

CPHS STATEMENT

This study (HSC-__-__-___) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.

Houston Department of Health and Human Services

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AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

Patient's Name: _____
Last First Middle
Maiden

Date of Birth: ____/_____/_____ Contact Number: _____

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1. I hereby authorize

- Any and all Harris County Hospital District Community Health Centers
- Any and all Houston Department of Health and Human Services Health Centers
- Any and all Legacy Community Health Services Clinics
- _____
  (Name of Physician/Clinic/Hospital/Institution, etc.)
- _____
  (Name of Physician/Clinic/Hospital/Institution, etc.)
- _____
  (Name of Physician/Clinic/Hospital/Institution, etc.)
- _____
  (Name of Physician/Clinic/Hospital/Institution, etc.)

to release copies of all labs and related reports of the above named patient for the time period _____ to present.

2. This information shall be released to: Houston Department of Health and Human Services, Bureau of Epidemiology, 8000 N. Stadium Drive, Houston, Texas, 77054.

3. The Purpose of Disclosure is at the request of the above named patient as a participant in the research study, "Assessing the Accuracy of Self-Reported HIV Testing Behavior," approved by the Committee for the Protection of Human Subjects of the University of Texas Health Science Center at Houston (HSC-___-___-___).

4. I understand that this request can be cancelled in writing. HDHHS, the above named facilities, and their employees will not be liable for releases made before I cancel this request.

5. I understand that when the information is released based on this request; it may be subject to re-release by the recipient and may no longer be protected health information.

6. I understand that the medical information indicated above may contain extremely private information including Human Immunodeficiency Virus (HIV) and other sexually transmitted diseases (STD) test results.

7. I understand that this release is valid until the conclusion of the research study. I can indicate an earlier expiration date here: _____.

_____ _____ _____
Date Signature of Patient/Parent/Guardian Relationship if not Patient

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