Form Approved
OMB No. 0920-1091
Exp. Date XX/XX/XXXX

Attachment 4 Sample Consent Form

Using Rapid Assessment Methods to Understand Issues in
HIV Prevention, Care and Treatment in the United States

Consent to be a Research Subject

Title:

Investigator:

Sponsor's Name: Centers for Disease Control and Prevention is funding this research.

Introduction/Purpose:
We would like to ask you to join a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.

Overview of the Study:
The purpose of the study is to learn about the care and treatment of people who have HIV. We want to find out about the problems people might have with HIV medicines and going to their HIV doctors or clinics. You are being asked to join this study because you are a person who is living with HIV and who may take HIV medicine or you may be a partner of a person living with HIV. We plan to talk with about 100 people over the next few months who will tell us how to improve the treatment and care of people who have HIV.

Procedures:
The interview will take about 1 hour of your time. An interviewer will arrange to meet you in a place that is easy for you. During the interview, we will ask you questions about you or your partner's HIV care. We will also ask you to fill out a brief survey about HIV care and you or your partner's life. There are no wrong or right answers. You do not have to answer any questions that make you uneasy.

Audio recording:
The interviewer will take notes and will record what you say. Afterward we will write up the interview and we will not use your name. At the end of the study, the recording of your interview will be destroyed.

Risks: There are no known risks to you for joining this study. It is possible that you will feel uneasy about some of the questions. You do not have to answer if you do not want to and you can stop the interview at any time. If you decide you do not want to continue in the study, please let the interviewer know. The biggest risk in this study is if any of your identifiers could be lost or viewed by people not in the study. To stop this from happening, we will ask you to use only first names of people you mention. We will not use your name on any forms. Instead, we will give you a study code number and we will keep your interview forms and tape of the recording in a locked cabinet. Only researchers can look at your interview. When we type up your interview, we will not use your name and we will take out any names you say and we will keep your interview in a password-protected computer file. Only authorized staff can access this information.

Benefits: There are no direct benefits to you for taking part in this interview. The information you give us will be used to help people with HIV get better care and treatment. You may feel a benefit from telling your story with a person who is interested in hearing what you have to say.

Privacy: If you chose to take part in this study, we will keep your information private to the extent allowed and required by law. We will use a study number rather than your name on your interview and study records. Your name will not be linked to your interview answers and will not be on the forms you complete. Your name and other facts that might point to you will not appear when we present this study or publish its results. If you tell us that you intend to carry out harm to yourself or to others, we are required by law to report this. We are also required to report suspected or actual child abuse. We are required by law to make sure that you and/or others are safe. If you need help with other emotional issues that come up, we will provide you with a list of services in your local area.

Authorization to Use and Disclose Health Information:
Some people outside of the study are authorized to look at your interview. The CDC and the Emory University Institutional Review Board (IRB) have the right to look at your study records to make sure that this research study is being done properly. In addition, records can be opened by court order or produced in response to a subpoena or a request from a judge. If you agree to join this study, you are giving permission to study staff to share your information with others on this study. This information could include your health information and personal identifiers. You have the right to withdraw from this study at any time. If you do this, you must contact Dr. Paula Frew, 500 Irvin Court, Suite 200, Decatur, GA 30030 at 404-712-8546 or pfrew@emory.edu. Even if you decide to leave the study, the researchers may still use your information. Your protected health information may be collected and kept as part of the study. The expected end date of this study is October 27, 2014.

Health Insurance Portability and Accountability Act (HIPAA)

You are being asked to be in a research study that includes private health identifiers. This section of the form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and stop the interview.** The decision to be interviewed or not be interviewed will not cause you to lose any medical benefits. The privacy of the study identifiers will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research identifiers from disclosure.

Authorization to Use and Disclose Protected Health Information The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use your PHI for the main study.

PHI that will be used:
The PHI that we will use (share) for the research study includes:

- HIV Status
- Medication Use
- Other Health Conditions

Purposes for which your PHI will be used:

We will use your PHI for conducting research. Your HIV status and use of medications will help us to determine your eligibility for this study, and will guide the questions that we ask during this interview.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. If you do not authorize the use of your PHI for the interview you will not be interviewed.

People that will Use Your PHI:
The following people and groups will use your PHI in connection with the research study:

- The Principal Investigator and the research staff will use your PHI to conduct the study.
- The Centers for Disease Control and Prevention is the Sponsor of the study. The Sponsor will NOT have access to your PHI.
- The following people and groups may use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB.

Information without identifiers may be used or disclosed with other people or organizations and/or for other purposes besides this study.

In Case of Injury

Emory and the sponsor have not set aside any money to pay you or to pay for medical treatment if you are injured during the course of this interview. If you believe you have become ill or injured from this interview, you should contact Dr. Paula Frew at telephone number 404-712-8546. You should also let any health care provider who treats you know that participated in this interview.

Costs: There is no cost to you to take part in this study. For joining this study, we will give you $40 in cash or as a gift card.

Contact Persons*:* If you have any questions about this study, please call Dr. Paula Frew at 404-712-8546 or the Emory University Institutional Review Board at 404-712-0720 or 1-877-503-9797 if you have any questions about your rights as a person in this research study.

Voluntary Participation and Withdrawal: Your participation in this study is voluntary. You have the right to refuse to be in this study. You have the right to stop being in this study at any time after you give your consent. Your decision will not affect in any way the care, treatment, or services that you currently receive or may receive in the future. We may stop you from continuing the study at any time if we decide that it is in your best interest. We may also stop you from participating in the study at any point if you do not follow study instructions.

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

_____
Subject's name (Please Print)

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Person Obtaining Consent	Date	Time