Tab 13
INFORMED CONSENT (Phase 2 Study)

Flesh-Kincaid 7.5

INFORMED CONSENT

This is an informed consent form. It will tell you about a study that is being conducted at this clinic. I will read this form to you. Please follow along with your copy and ask questions if things are not clear.

A. Purpose of the Study

You are being asked to take part in a research study. The study is being done by [name of Institution], the Centers for Disease Control and Prevention, and the Health Resources and Services Administration.

The purpose of the study is to learn whether additional services offered to some patients will help improve their attendance at this clinic. These additional services will be provided by 2 study staff persons. These persons will meet briefly with some patients after their medical exams, and at other times if needed, and help patients overcome obstacles to coming to the clinic.

We hope that 300 patients at this clinic will take part in this study. We expect a total of 1800 patients to join the study at the six clinics taking part in this study. These six clinics are located in Birmingham, Houston, Miami, Brooklyn, Boston, and Baltimore.

Before you decide if you want to be in this study, I want to tell you more about what is means to be part of the study. Please ask me any questions you may have.

B. Study Procedures

If you join the study, you will do a survey today. The survey will take about 30 minutes to do. All patients who join the study will do this survey. We will use a computer to ask you the survey questions.

In addition to doing the survey, some patients who join the study will meet with the study staff persons. Patients will be chosen by chance (like flipping a coin) to see who meets with these persons. Patients who are not chosen to meet with the study staff persons will continue to receive their regular medical care and services already available to all patients at this clinic.

If you are chosen to meet with the study staff persons, you will stay today for about 30-45 more minutes after you do the survey. You will meet with one or both of these persons. They will ask you questions about things in your life that may stop your from coming to

the clinic. They will give you information and assistance that may help you come to the clinic for your medical care. Some of the information that you give to the study staff persons may be shared with other clinical staff to help with your care. Each time you come to the clinic for a medical exam in the next 12 months you will meet with one or both of the study staff persons for about 15-45 minutes. You will be asked to provide information about how we can contact you. With your permission, study staff may call you on the phone, send you e-mail or regular mail, or meet with you outside the clinic over the next 12 months. Letters and phone calls will be used to help us stay in touch with you and to remind you of your medical appointments. Your private medical information will not be written in any letters or left in voice mail.

For all patients in this study, we will need to get limited HIV medical data (CD4 count, viral load, dates of tests) and clinic attendance data from medical records during the next 18 months. We will use lab tests that are part of your regular medical care at this clinic. You will not have any blood drawn as part of this study. The data will be used in the analysis of this study. Only a code number, not your name, will be used to identify the data.

C. Risks

There are minimal risks to you if you take part in the study. A few questions on the computer survey ask about alcohol and drug use and may make you feel uncomfortable. None of the information from the computer survey will be given to your medical providers. You may refuse to answer any question in the computer survey.

D. Benefits

There are no direct medical benefits to you by joining this study. Patients who are chosen to meet with the study staff persons will receive help in overcoming problems to coming to the clinic for HIV care.

The results from this study may help us improve services given to patients at this clinic.

E. Protecting your Privacy

All of the information you give us will be kept private to the extent allowed by law. This study has a Federal Certificate of Confidentiality. This means we cannot be forced to give out any information such as medical information, survey information, or other information that can identify you.

Only a code number, not your name, will be used in the computer survey and on study materials. All of the surveys from the patients in this study will be kept on a computer or storage device that is protected by a password. All study materials will be stored in a locked file cabinet.

Any contact information collected from you as part of this study will be destroyed within 1 month after you finish the study. After your information is destroyed, there will be no way to link you personally to your survey or to other study materials.

When we write about the results of this study, we will use only numbers and not names or personal facts. No one will be able to link the results back to you. We will do this to keep your personal information private.

F. Voluntary Participation

You are free to join the study or not. If you do not join, you will not lose any services or medical care at this clinic. If you decide to join the study, you are also free to drop out later for any reason. In that case too, you will not lose any services or medical care at this clinic. We will not let you be a part of the study if you are not able to give legal consent to be in the study.

You may refuse to answer any question or simply not talk about a matter that you do not wish to discuss.

G. Costs

There is no cost to you for being in this study.

H. Reimbursement

We will give you $20 cash after you complete the computer survey as a thank you for your time. There will be no other reimbursements. (Note: some sites will be giving $30 cash and some sites will be giving gift cards instead of cash.)

I. Compensation for Injury

There are minimal risks to you if you take part in this study. If you are injured as a result of this study, the study staff will help you get medical care. The cost for that medical care will be billed to you or your insurance company, just as for any other medical care. [Site name] and CDC do not pay you for these costs. However, by signing this form you are not giving up any of your rights.

J. Questions

If you have questions about this study or if you think you have been harmed as a result of being in this study, you can contact [local contact person (s), phone number (s) and institution (s)].

If you have questions about your rights as a research subject, you may contact the head of the [Local Institutional Review Board], at [phone number]. You may also contact the office of CDC's Deputy Associate Director for Science at 1-800-584-8814. You can leave a brief message with your name, phone number, and the CDC protocol number #XXXX for this project.

K. Ending Your Participation

If you decide to join the study, you are free to drop out later for any reason. We will not let you be a part of the study if you are not able to give legal consent to be in the study. If you are not part of this study, you will not receive any reimbursement.

L. Duty to Protect

If you tell us that you plan to harm yourself or another person, we are required to contact the proper authorities.

M. Agreement

I have read (or someone has read to me) the information above. I have been given the chance to ask questions and all of my questions have been answered. I agree to be in this study.

_____	_____
Date	Participant's signature or initials

_____	_____
Date	Signature of person obtaining consent