Attachment 7

MMP Model Informed Consent Form

Medical Monitoring Project
Statement of Informed Consent

You have been asked to participate in this project because you have HIV. Participation in this project is voluntary. You choose to participate or not to participate. You do not have to be in the project if you do not want to be. You may leave the project at any time. Leaving the project will not result in any penalty or loss of benefits to which you are entitled.

Why we are doing this project

HIV is the virus that causes AIDS. Your health department, together with the Centers for Disease Control and Prevention (CDC), is doing this project to learn more about people who are infected with HIV and the types of services they use and need. This information will help us improve programs to prevent other people from getting HIV and improve services for those who already have HIV. Data from this project will be used to identify needed care and treatment services and to plan targeted HIV prevention interventions and programs. The authority for this data collection is provided by section 306 of the Public Health Service Act.

What we will need from you _

If you choose to be in this project, we will

- ask you questions.
- look at your medical records.

The questions

Answering the questions will take about 45 minutes. You do not have to answer any question you do not want to answer.

The questions will ask about your

- medical past
- use of medical and social services
- sex practices
- use of drugs and alcohol
- reproductive history (if you are a woman)
- ability to work and take care of yourself and your family

Although we send the answers to CDC, we do not send any information that could identify you or be traced back to you. Your answers will be kept confidential, identified only by a code number, and kept in a locked file that only project staff can open.

Your medical records

As part of routine public health surveillance, we will also look at your medical record to collect clinical information about your HIV infection. This information will include illnesses you have had, medicines you have taken, and care you have received. Again, we do not send any information to the CDC that could identify you or be traced back to you. Information from your medical records will be linked to your answers only by a code number.

What you can expect from us

Privacy

We protect your privacy. All information you give us will be kept private and confidential and will not be shared or disclosed without your consent. Your answers will be grouped together with answers from other participants so that no one will know which answers came from you. We will send information from this project to CDC, but we will not send any information that could identify you. Section 308(d) of the Public Health Service Act protects the confidentiality of this information kept at CDC.

Payment

If you answer the questions and agree to let us review your medical records, you will receive the equivalent of $25.00 as payment for your time and effort. If you later choose to leave the project, you may keep the money.

Things to consider

- There is no cost to you (other than your time and effort) for participating in this project.
- If you would like, we can give you information about how to avoid giving HIV to someone else.
- If you would like, we can give you information about where to get medical and social services in your area.
- Although you will gain no direct benefits from taking part in this project, you will help us learn more so we can improve services available to other people with HIV and AIDS.
- Some of the questions may make you feel uncomfortable or may be too personal. Remember: You do not have to answer any questions you do not wish to answer.

Questions?

About this project, please

- ask the person who asks you the interview questions
- call (local principal investigator) at (phone number). _

About your rights, please contact

- **The institutional review board (IRB) at (State/Local Health Department)**

at (phone number).

- (Local IRB [?] contact) at (phone number)

- **CDC at 1-800-584-8814. This is a toll free call. Please leave a brief message including your name and phone number. Say that you are calling in reference to CDC's Medical Monitoring Project. Someone will return your call as soon as possible**.

Participant's Consent Statement

I agree to take part in the project described here. I have read the statement, and all my questions have been answered. I understand that my participation is completely voluntary.

_____ _____

Signature of Participant Date

_____ _____

Signature of Interviewer Date

MMP October 2006