Medical Monitoring Project
Statement of Informed Consent

The following statement must be read to all potential participants:

You have been selected to participate in this project because you have HIV. Participation in this project is voluntary. If you decide to take part, you may leave the project at any time. There are no penalties or loss of benefits if you choose not to take part or leave the study early.

Why we are doing this project

HIV is the virus that causes AIDS. The Michigan Department of Health and Human Services, together with the Centers for Disease Control and Prevention (CDC), is doing this project to learn more about people who are living with HIV and the types of services they use and need. This information will help us to improve programs that keep people healthy and provide the help they may need.

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 approximately one hour. 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 cis woman)
- ability to work and take care of yourself and your family

We send the answers to CDC, but we don't send them your name. Instead, we will assign a code number to your answers. We don't send the CDC any information that identifies you. We don't send the CDC any information that could trace back to you. Your answers are confidential. All project materials are kept in a locked cabinet or secure computer file that only project staff can open.

Your medical records

We will also look at your medical record to collect information about your HIV infection. This includes medicines you are taking, clinic visits, and lab test results. Again, we don't send the CDC any information that can identify you or that could trace back to you. A code number will link information from your medical records to your answers.

What you can expect from us

We protect your privacy. All information you give us will be kept private and confidential. Your records will be kept confidential as much as the law allows. 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 the CDC, but we will not send any information that could identify you. Federal law protects the confidentiality of information kept at CDC.

Token of Appreciation

If you answer the questions and agree to let us review your medical records, you will receive a $50 gift card as a token of appreciation for your participation. If you later choose to leave the project, you may keep this gift card.

Other things to consider

- There is no cost to you (other than your time and effort) for being in this project.
- If you like, we can give you information about where to get medical and social services in your area.
- There are no direct benefits from being in this project. However, the information you give us can help us improve services available to other people living with HIV.
- Some of the questions may make you feel uncomfortable or may be too personal. Remember: You don't have to answer any questions you don't wish to answer.

Also…

- A small number of interviews and medical record reviews will be observed by supervisors to provide feedback to MMP staff on their work.
- If more information is needed, a staff member may contact you later; however, this is unlikely.
- MMP is unable to reimburse you for minutes used to complete telephone interviews.

Questions?

About this project, please

- ask the trained staff member who is interviewing you
- call Mary-Grace Brandt, the Principal Investigator, at **517-335-0855**

About your rights, please contact

- The institutional review board (IRB) at The Michigan Department of Health and Human Services, at **517 241-1928**

Additional questions, please contact

- CDC at **1-404-639-6475**. Please leave a brief message including your name and phone number. Say that you are calling in reference to the 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, or have been read the statement, understand 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

Verbal Consent Obtained: Yes No Date:_____ Time:_____

MMP Staff:_____