

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. You can 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

The Texas Department of State Health Services (DSHS) together with the University of Texas Southwestern Medical Center and 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.

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 1 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 woman)
- ability to work and take care of yourself and your family

If we need more information, a staff member may contact you later.

Your medical records

As part of routine public health surveillance, we will also look at your medical records 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.

A small number of interviews and medical record reviews will be observed by supervisors to provide feedback to MMP staff on their work.

What you can expect from us

Privacy

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. There are federal and state laws to protect your confidentiality. These laws will be followed to the fullest extent. 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 or be traced back to you. Your answers will be identified only by a code number and kept in a locked file that only project staff can open. 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 voucher valued at \$75.00 as a token of appreciation for your participation. If you later choose to leave the project, you may keep the voucher.

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 on 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 interviewer
- call Jonathon Poe, Principal Investigator, at 512-533-3032, or Sylvia Odem, Project Coordinator, at 512-533-3053.

About your rights for this project, please contact

- **TX DSHS Institutional Review Board (IRB) at 1-888-777-5037.** The TX DSHS IRB determined that the project is public health practice and not research and as such does not require IRB approval.
- **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 the statement, understand the statement, and all my questions have been answered. I understand that my participation is completely voluntary.

Initials or Signature of Participant

Date

Signature of Interviewer

Date