

MMP ID _____

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 need to tell us if you want participate or not. You do not have to be in the project if you do not want to be. You may leave the project at any time. If you choose not to participate or leave the project there will be no change in the health care or other services you may receive.

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.

What we will need from you

If you choose to be in this project, that means

- You agree to let us ask you questions.
- You agree to let us combine your answers with information from your medical records on the health care you have received.

The questions

Answering the questions will take about 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 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 answers cannot be traced back to you. Although we send the answers to CDC, we do not send any information that could identify 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

We will ask your permission to use information from your medical records. This information will include illnesses you have had, medicines you have taken, and care you have received. Your medical records will not be identified as having come from you. They will be linked to your answers only by a code number.

What you can expect from us

Privacy

We will protect your privacy. All information you give us will be kept private and confidential. 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. Federal law protects the confidentiality of information kept at CDC.

Payment

For answering the questions and agreeing to let us review your medical records, you will receive \$50 as payment for your time and effort. If you decide later 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

- talk to the person who asks you the interview questions
- call Susan Buskin at 206-205-6123 or Elizabeth Barash at 206-296-2907
- 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 protocol # **04155**. Someone will return your call as soon as possible.

Interviewer's Consent Statement

I have described the project to the participant and they have agreed to take part in the project described here. The participant has read this statement, understands this statement, and all their questions have been answered. I have offered the participant a copy of this document.

PHSKC Interviewer's Signature

Date

RESPONSE CARDS

RESPONSE CARD A

<u>Monthly Income</u>		<u>Yearly Income</u>	
a.	\$0 to \$417	a.	\$0 to \$4,999
b.	\$418 to \$833	b.	\$5,000 to \$9,999
c.	\$834 to \$1250	c.	\$10,000 to \$14,999
d.	\$1251 to \$1667	d.	\$15,000 to \$19,999
e.	\$1668 to \$2500	e.	\$20,000 to \$29,999
f.	\$2501 to \$3333	f.	\$30,000 to \$39,999
g.	\$3334 to \$4167	g.	\$40,000 to \$49,999
h.	\$4168 to \$6250	h.	\$50,000 to \$74,999
i.	\$6251 or more	i.	\$75,000 or more

RESPONSE CARD B

I asked them <u>not to tell any</u> of my partners
I asked them <u>to tell only some</u> of my partners
I asked them <u>to tell all</u> of my partners
I told them that I did not have any partners

RESPONSE CARD C

HIV case management services

Counseling about how to prevent the spread of HIV

Medicine through the AIDS Drug Assistance Program (ADAP)

Professional help remembering to take your HIV medicines on time or correctly

HIV peer group support

Dental care

Mental health services

Drug or alcohol counseling or treatment

Public benefits including Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI)

Domestic violence services

Shelter or housing services

Meal or food services

Home health services

Transportation assistance

Childcare services

Interpreter services

Other HIV-related services

RESPONSE CARD D

Always

Most of the time

About half of the time

Rarely

Never

RESPONSE CARD E

Never	Rarely	About half of the time	Most of the time	Always
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RESPONSE CARD E-1

Never
Rarely
About half of the time
Most of the time
Always
Been on medications less than 30 days

RESPONSE CARD F

Within the past **week**

1–2 **weeks** ago

3–4 **weeks** ago

1–3 **months** ago

More than 3 **months** ago

Never skip medicines

RESPONSE CARD G

Not at all sure	Somewhat sure	Very sure	Extremely sure
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	1	2	3

RESPONSE CARD H

RESPONSE CARD H

Very dissatisfied	Somewhat dissatisfied	Somewhat satisfied	Very satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	1	2	3

RESPONSE CARD I

Not at all	A little	Somewhat	A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	1	2	3

RESPONSE CARD J

Daily	Weekly	Monthly	Less than Monthly	Never
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ALCOHOL RESPONSE CARD



Not at all

Several days

More than half the days

Nearly every day

RESPONSE CARD L

0–49

50–99

100–199

200–349

350–499

500 or more

RESPONSE CARD M

Below the level of detection, undetectable

Detectable but less than 5,000 viral copies/ml








5,000 to 100,000 viral copies/m

Greater than 100,000 viral copies/ml










RESPONSE CARD N

Strongly disagree...Somewhat disagree...Neutral/no opinion...Somewhat agree...Strongly agree






Nucleoside/Nucleotide Analogue Reverse Transcriptase Inhibitors (NRTI)

<p>Emtriva* (emtricitabine, FTC)</p> 	<p>Epivir* (lamivudine, 3TC)</p> 	<p>Retrovir* (zidovudine, AZT, ZDV)</p> 	<p>Videx EC (didanosine, ddl)</p> 	<p>Viread (tenofovir, TDF)*</p> 	<p>Zerit* (stavudine, d4T)</p> 	<p>Ziagen* (abacavir, ABC)</p> 
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Protease Inhibitors (PI)

<p>Aptivus (tipranavir, TPV)</p> 	<p>Crixivan (indinavir, IDV)</p> 	<p>Invirase (saquinavir hard gel capsules, SQV)</p> 	<p>Kaletra* (lopinavir/ritonavir, LPV/r)</p> 	<p>Lexiva (fosamprenavir, FPV)</p> 
<p>Norvir* (ritonavir, RTV)</p> 	<p>Prezista (darunavir, DRV)</p> 	<p>Reyataz (atazanavir, ATV)</p> 	<p>Viracept (nelfinavir, NFV)</p> 	

Fixed Dose Combinations

<p>Atripla (TDF+FTC+EFV)</p> 	<p>Combivir (AZT plus 3TC)</p> 	<p>Epzicom (ABC plus 3TC)</p> 
<p>FDA Pregnancy Category D</p>		
<p>Trizivir (AZT plus 3TC plus abacavir)</p> 	<p>Truvada (TDF plus FTC)</p> 	

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)

<p>Intellec (etravirine, ETV)</p> 	<p>Rescriptor (delavirdine, DLV)</p> 
<p>Sustiva* (efavirenz, EFV)</p> 	<p>Viramune* (nevirapine, NVP)</p> 

FDA Pregnancy Category D

Entry Inhibitors


<p>Fuzeon (enfuvirtide, T-20) Fusion Inhibitor</p> 	<p>Selzentry (maraviroc, MVC) CCR5 Antagonist</p> 
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Discontinued Medications or Formulations

<p>Agenerase (amprenavir, APV)</p> 	<p>Fortovase (saquinavir soft gel capsule, SQV)</p> 	
<p>Hivid (zalcitabine, ddC)</p> 	<p>Kaletra (lopinavir/ritonavir, LPV/r)</p> 	<p>Videx (didanosine, ddl)</p> 

Integrase Inhibitors

Isentress
(raltegravir, RAL)



*Also available in liquid form

MMP Local Questions Response Cards

Response Card A Income

<u>Monthly Income</u>	<u>Yearly Income</u>
1. Less than \$902	1. Less than \$10,830
2. \$903 to \$1,353	2. \$10,831 to \$16,245
3. \$1,354 to \$1,805	3. \$16,246 to \$21,660
4. \$1,806 to \$2,256	4. \$21,661 to \$27,075
5. \$2,257 to \$2,707	5. \$27,076 to \$32,490
6. \$2,708 or greater	6. \$32,491 or greater

Response Card B Barriers to Accessing Care

No Barriers to accessing medical care
The location is too far from my home
It is difficult to get a bus from my home to my medical provider
The hours of my medical provider conflict with my work schedule
I felt too ill to get other transportation
Other
I don't have an HIV provider
Don't know
Refuse to answer

Response Card C

ARV Adherence

Never miss a dose

Miss a dose about once a month

Miss about 2 doses a month

Miss about 3 doses a month

Miss a dose about once a week

Miss a dose about 2-3 times a week

Miss a dose about 4-5 times a week

Miss a dose about 6-7 times a week

Miss a dose more than once a day

Don't know

Refuse to answer

Response Card D

Medical Services – Select FIVE Most Important to HIV-related Health

Interviewer instructions:

1. Have participant choose the FIVE most important to HIV-related health

Select FIVE only

Dental Care	
Drug or alcohol counseling or outpatient treatment	
Help paying for health insurance	
Help paying for HIV medications (ADAP/EIP)	
HIV case manager/social worker	
Home health aide (in your home or other residential setting)	
Hospice care (end of life care)	
Medical care (doctor, nurse, etc.)	
Methadone vouchers	
Nutrition counseling/Dietician	
Professional mental health counseling or therapy	
Don't know	
Refuse to answer	

Response Card E

Medical Services – Current Use/Access

1. Determine CURRENT Need/Use of All Medical Services
2. If participant is unable to access service, determine the MAIN reason

	I don't need or use it	I use it now or have in the past year	I need it but can't get it
Dental Care			
Drug or alcohol counseling or outpatient treatment			
Help paying for health insurance			
Help paying for HIV medications (ADAP/EIP)			
HIV case manager/social worker			
Home health aide (in your home or other residential setting)			
Hospice care (end of life care)			
Medical care (doctor, nurse, etc.)			
Methadone vouchers			
Nutrition counseling/Dietician			
Professional mental health counseling or therapy			
Don't know			
Refuse to answer			

Response Card F

Medical Services: Main Reason Unable to Access Services

Have not looked for the services

Have been told I am ineligible for this service due to my income

Have been told I am ineligible for this service due to my health status

Service does not seem to exist

Service is not available at a time when I can access it

Service is not available at a location where I can access it

Had a bad experience accessing this service

I could not find a provider of this service who takes Medicaid (or other insurance)

Other

Don't know

Refuse to answer

Response Card G

Support Services – Select **THREE** most important to HIV-related health

Interviewer instructions:

1. Select up to **THREE** services

Select THREE only

Bags of groceries	
Child care during HIV-related appointments	
Drug or alcohol inpatient treatment	
Emergency HIV medications when you have lost yours	
Help finding housing	
One-on-one emotional support	
Physical therapy	
Prepared meals (when you are unable to prepare meals because of your health)	
Rides to and from medical appointments	
Safer sex information or support (such as one-to-one prevention counseling)	
Short term place to live in case of a medical emergency	
Speech therapy and/or low-vision training	
Support groups	
Telephone referrals to doctors or dentists	
Temporary/transitional housing	
Treatment adherence counseling (help taking your medications)	

Response Card H

Support Services – Current Use/Access (Page 1 of 2)

Interviewer instructions:

1. Determine CURRENT Need/Use of All Support Services
2. If participant is unable to access service, determine the MAIN reason

	I don't need or use it	I use it now or have in the past year	I need it but can't get it
Bags of groceries			
Child care during HIV-related appointments			
Drug or alcohol inpatient treatment			
Emergency HIV medications when you have lost yours			
Help finding housing			
One-on-one emotional support			
Physical therapy			
Prepared meals (when you are unable to prepare meals because of your health)			
Rides to and from medical appointments			
Safer sex information or support (such as one-to-one prevention counseling)			
Short term place to live in case of a medical emergency			
Speech therapy and/or low-vision training			
Support groups			
Telephone referrals to doctors or dentists			

Response Card H

Support Services – Current Use/Access (Page 2 of 2)

Interviewer instructions:

1. Determine CURRENT Need/Use of All Support Services
2. If participant is unable to access service, determine the MAIN reason

	I don't need or use it	I use it now or have in the past year	I need it but can't get it
Temporary/transitional housing			
Treatment adherence counseling (help taking your medications)			
Don't know			
Refuse to answer			

Response Card I

Support Services: Main Reason Unable to Access Services

Have not looked for the services

Have been told I am ineligible for this service due to my income

Have been told I am ineligible for this service due to my health status

Service does not seem to exist

Service is not available at a time when I can access it

Service is not available at a location where I can access it

Had a bad experience accessing this service

I could not find a provider of this service who takes Medicaid (or other insurance)

Other

Don't know

Refuse to answer