

Appendix 14

Informed Consent Forms

Baylor College of Medicine

Written informed consent was not required for any of the project elements by the BCM Institutional Review Board

University of Miami

Consent to Participate in a Research Study

Title of Study: Comprehensive HIV Clinic Based Intervention to Improve Patients' Health and Reduce Transmission Risk

Sponsor: Centers for Disease Control and Prevention and
The National Institute of Mental Health

Principal Investigator: Allan E. Rodriguez, M.D.
1120 NW 14th Street, Suite 856
Miami, FL 33136

Study-Related

Phone Numbers: Allan Rodriguez, MD
305-243-3011 or 305-243-1000 (24 hour page operator)
305 955-1205 (Pager)

Email: arodriguez2@med.miami.edu

Site(s): Jackson Health Centers – Ambulatory Care Center (ACC)

Study Coordinator: Kathleen Mercogliano, RN
305 243-5355 (Office)

READ THE FOLLOWING CAREFULLY

This consent form contains information, which could help you decide if you wish to take part in this research study.

You are being asked to voluntarily participate in a research study. Before you give your consent to be part of this study, please read the following information and ask as many questions as necessary to be sure that you understand what your participation in this research study will involve.

The study is being done by The University of Miami, the Centers for Disease Control and the National Institute of Mental Health.

Background:

In this study, you and other study participants will receive research intervention services. The goal of the study is to determine whether these services will improve your health by lowering the amount of HIV in your body.

You will receive these services at this clinic when you come for your regularly scheduled medical appointments and possibly at other times if they are convenient for you. These services will be available at this clinic for approximately 186 months.

PURPOSE

The purpose of the study is to learn whether research intervention services offered to some patients with HIV and with a detectable viral load, will help improve their

health by lowering the amount of HIV in their body. These services are being offered to everybody attending this clinic and will be available for approximately 18 months.

These intervention services will focus on the importance of following your doctor's recommendation about taking HIV medications, the importance of coming regularly to clinic for your medical care, and the importance of safe sex practices, if these are needed. These intervention services will include answering a few questions on a computer and viewing short videos, also on the computer. This is called a "computer intervention."

You and some other patients may also be offered private one-on-one counseling from a counselor at this clinic. These intervention services will be offered to you and other patients when you come to the clinic and at other times if needed. Before you decide if you want to volunteer to be in this study, I want to tell you more about what it means to be part of the study. Please ask me any questions you may have at any time.

NUMBER OF STUDY PARTICIPANTS

We hope that approximately 3,500 patients that come to this clinic will take part in this study. Approximately 1,000 will participate in the computer intervention and 500 will meet the counselor.

There are six clinics taking part in this study. These six clinics are located in Birmingham, Houston, Miami, San Diego, Boston and Seattle.

DURATION OF STUDY

The total duration of the study in the clinic will be approximately 18 months.

PROCEDURES

You have already undergone a screener (completed a screening informational form) before your scheduled clinic visit. Based on your lab results you are being asked to do the following:

1. Computer Based Intervention (CBI)

If you join the study, you will do the private computer based intervention (CBI) (takes about 10 minutes) today (same day as your scheduled clinic visit). The next time you come to the clinic you will do the computer based intervention again. The computer will ask questions about how you are doing with taking your HIV medications (if you take HIV medications), how you feel about coming to the clinic for medical care. There are also questions about recent sexual behavior.

Your answers will be private and you will be identified by a code number, not your name. None of the clinic doctors, nurses or other clinic staff will see your answers.

2. Video(s)

After you answer the questions, the computer will show you 1 or more short videos. These videos are about taking HIV medications, coming to clinic for HIV medical care, and safe sex behaviors.

In the future, patients (you may be one) will be offered private one-on-one counseling from a trained counselor (Health Coach- (HC)) at this clinic. This counseling will focus on ways to help you and the other patients take HIV

medications, come regularly to clinic for HIV medical care, and have safer sex. The counseling session will last about 60 minutes and you will have two (2) other counseling sessions on separate days. During this counseling session you will be asked to do the computer based intervention questions (about 5 minutes) in private, but not view the videos. The counselor will not see your answers to the computer questions. You will receive a list of some tips that might benefit you. The counselor (HC) will ask you to provide information about how he/she can contact you to see how you are doing. With your approval, the health coach may call you on the phone, send you letters, email or text you, whatever works best for you. Your private medical information will not be written in any letters, e-mails or left on any voice mail.

The counselor (HC) will work with you to determine which methods of contact will be most helpful for you and also protect your privacy.

The counselor (HC) will meet with and counsel you after your medical exams, for three visits 1-3 weeks apart.

After the counselor (HC) has consulted with your medical provider he/she will offer counseling sessions with focus primarily on these three main behavioral areas:

- Adherence to Anti-retroviral treatment (ART)
- Regular care (attending clinic on a regular basis)
- Risk related reduction (sexual risk reduction)

The counselor will work with you to determine which methods of contact will be most helpful for you and also protect your privacy.

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

RISKS AND DISCOMFORTS

There are minimal risks to you if you take part in the study. A few of the computer questions may ask about your sexual behavior and may make you feel uncomfortable. None of the answers to the computer questions will be seen by your medical provider or by any clinic staff. You may also refuse to answer any of the computer questions if you choose to do so.

Information shared with your study counselor will be kept private and will not be shared with any other person. The only information the research staff will know is the date and time of your counseling session.

Participants Costs and Reimbursements.

There is no cost to you for being in this research study. **If you have a one-on-one counseling session you will be given \$10.00 as a token of appreciation.** There is no other reimbursement/payment.

BENEFITS

Research is designed to benefit society by gaining new knowledge. There may be no direct medical benefits to you by joining this study. If you are chosen to meet

with the counselor (HC) you will receive help in overcoming problems in coming to the clinic for HIV care.

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

COMPENSATION FOR STUDY-RELATED INJURY

Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. The University of Miami and CDC do not pay you for these costs. By signing this form you are not giving up any of your rights.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM STUDY

You are free to join or not join the study. If you do not join the study, you will not lose any services or medical care you receive from the study doctor or UM/Jackson Memorial Hospital. If you are not part of this study, you will not receive any reimbursement.

If you decide to join the study, you are also free to drop out of the study at any time for any reason. You must tell your doctor, study coordinator, or counselor (HC) if you wish to stop taking part in the study. If you drop out of the study you will not lose any services or medical care at this clinic.

Your participation in this study may be discontinued, without your consent, at any time by the study doctor, if he/she believes that participation in the study is no longer in your best interest. The Institutional Review Board (IRB), regulatory authorities, or the sponsor may also discontinue your participation in the study. You will not 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.

Privacy

By signing this consent, you authorize the Investigator and his staff to access your medical records and associated information as may be necessary for purposes of this study. All of the information you give us will be kept private to the extent allowed by law. The Department of Health and Human Services (DHHS) may review these research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of **privacy**.

If it is noticed that there is a risk of harm to yourself or others, we will disclose this information to the proper authorities.

Only a code number, not your name, will be used in the computer survey and on any study data. Your answers to the computer questions will not be stored on the computer or on any storage device at the CDC. Only your specific code number will be sent with your data to the CDC. The data sent to the CDC will not include your name or any other way for the CDC to identify you.

The study staff will use your information (your phone number or address) on record at the clinic. Any information that could link you as a participant in this study will be destroyed after the study is completed. After your information is destroyed, there will be no way to link you personally to your counselor, counseling 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.

The study site personnel may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

WHOM TO CONTACT

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 **Dr. Allan E. Rodriguez** at **305-243-3011** or **305-243-1000 (24 hour page operator)**, or the study coordinator **Kathy Mercogliano** at **305 243-5355**.

If you have questions about your rights as a research subject, you may contact **the University of Miami's HUMAN SUBJECTS RESEARCH OFFICE (HSRO)**, at **305-243-3195**. You can leave a brief message with your name, phone number, and name of the study.

AGREEMENT OF DECISION TO PARTICIPATE

I will receive a copy of this signed informed consent form.

I have read this consent form, which is printed in English or Spanish (a language which I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study, risks and discomforts have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to take part in this research study.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

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Boston Medical Center

*BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH, DENTAL MEDICINE AND
THE BOSTON MEDICAL CENTER*



RESEARCH CONSENT FORM HIV Positive Prevention Co-Principal Investigators: Margaret Sullivan, MD; Mari-Lynn Drainoni, PhD

Background

You are being asked to take part in a research study. In this study, participants will be given research intervention services that may help them improve their health by lowering the amount of HIV in their body. You are being asked to participate because you may benefit from such services. You will receive these services at this clinic when you come for regularly scheduled medical appointments and possibly at other times if convenient for you. The services will be available at this clinic for approximately 18 months.

The study is being conducted by Boston University Medical Center, the Centers for Disease Control and Prevention (CDC), and the National Institute of Mental Health.

Purpose

This consent form 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.

The purpose of the study is to learn whether research intervention services offered to some patients will help improve their health by lowering the amount of HIV in their body. The services will focus on the importance of following your doctor's recommendations about taking HIV medications, coming regularly for medical care, and the importance of safer sex practices if needed. These intervention services will include answering a few questions on a computer and viewing short videos on a computer. This is called a "computer intervention." Some patients may also be offered private one-on-one counseling from a counselor at this clinic. These intervention services will be offered to patients when they come to the medical center and at other times if needed. We hope that up to 500 patients at this clinic will take part in this study. We expect patients to join the study at the six HIV clinics taking part in this study. These six clinics are located in Birmingham, Houston, Miami, San Diego, Boston, and Seattle. Before you decide if you want to be in this study, I want to tell you more about what it means to be part of the study. Please ask me any questions you may have.

What Happens In This Research Study

Computer Intervention: If you join the study, you will do the computer intervention, or CBI, today. The CBI takes about 10 minutes. The next time you are at the medical center you will do the computer intervention again. The computer will ask you a few questions about how you are doing with taking your HIV medications (if you take these), how you feel about coming to the clinic for HIV medical care.. There are also questions about recent sexual behavior. Your answers will be private and will be identified by a code number only. Your name will not be included. None of the doctors, nurses, or clinic staff will see your answers.

After you answer the questions, the computer will show you 1 or more short videos. These videos are on taking HIV medications, coming to clinic for HIV medical care, and safer sex behaviors.

Health Coach: In the future, some patients will be offered private one-on-one counseling from a trained health coach at this clinic. The health coach will focus on ways to help patients take HIV medications, come regularly to clinic for HIV medical care, and have safer sex as needed. A counseling session will last about 60 minutes and patients will have 3 counseling sessions on separate days. After the third counseling session, patients will be asked to do the computer intervention questions in private, but not view the videos. This will take about 5 minutes.

If you are offered one-on-one counseling, the health coach will not see your answers to the computer questions. You will receive a list of some tips that might benefit you.

The health coach will ask you to provide information about how he/she can contact you to see how you are doing. With your approval, the health coach may call you on the phone, send you letters, email or regular mail, whatever works best for you. Your private medical information will not be written in any letters or left on voice mail. The health coach will work with you to determine which methods of contact will be most helpful for you and also protect your privacy.

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 your medical records at this clinic. You will not have any blood drawn as part of this study. We will use lab tests that are part of your regular medical care at this clinic. The data will be used in the analysis of this study. Only a code number, not your name or your medical record number, will be used to identify the data.

You are free to choose not to participate in part or all of this study and your decision will not affect the care you receive in the clinic.

Risks and Discomforts

There are minimal risks to you if you take part in the study. A few of the computer questions ask about sexual behavior may make you feel uncomfortable. None of your answers to the computer questions will be seen by your medical providers or by any clinic staff. You may refuse to answer any of the computer questions.

Information you share with the health coach will be kept private and will not be

shared with any other persons. The research staff will only know the date and time of a counseling session. There is a small risk of some loss of privacy, although the study staff is dedicated to minimizing this risk.

Participant Costs

There are no costs to you for participating in this research study. We will offer you a \$10.00 token of appreciation if you have a meeting with the health coach or to complete the computer-based intervention that is not at the time of another appointment at Boston Medical Center. There will be no other reimbursement for study participation.

Privacy

All of the information you give us will be kept private to the extent allowed by law. Only a code number, not your name, will be used in the computer survey and on your study data. Your answers to the computer questions will not be stored on the computer or on any storage device at this clinic. Instead, your answers are immediately sent to a highly secure storage device at the CDC.

The research staff will use your contact information (like your phone number or address) that is on record at the clinic.

When the study is over, information that can potentially link you as a participant in the study will be destroyed. There will be no way to link you personally to your computer survey or to other study data.

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.

OPTIONAL FUTURE STUDIES:

If you choose to be in this study, we would like to contact you in the future to let you know about new opportunities to take part in future studies. If you choose not to be contacted in the future about other studies, you can still take part in this study. By checking yes and writing your initials below, you allow the researchers to contact you in the future to let you know about other studies.

_____ Yes _____ No _____ Initials

IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you

voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject (Signature and Printed Name) Date

Person Obtaining Consent (Signature and Printed Name) Date

-----**Use the following only if applicable**-----

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

Printed name of Impartial Witness Signature Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

University of Alabama, Birmingham

CONSENT FORM

TITLE OF RESEARCH: Implementation and Evaluation of a Comprehensive Prevention with Positives Intervention at HIV Clinics

IRB PROTOCOL: X130715003

INVESTIGATOR: Michael J. Mugavero, MD, MHSc

SPONSOR: Centers for Disease Control and Prevention (CDC)

Purpose of the Research

We are asking you to take part in a research study. The purpose of this document is to give you information that you will need to help you decide whether or not to be in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this document that is not clear. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called “informed consent.”

This is a research study sponsored by the Centers for Disease Control and Prevention (CDC). The purpose of the study is to evaluate a clinic-based intervention aimed toward improving health outcomes for patients at this clinic, as well as improve patients’ adherence to antiretroviral therapy (ART), retention in care, and safer-sex practices. Most patients from the University of Alabama at Birmingham 1917 Clinic are eligible to participate.

We hope that approximately 700 patients at the 1917 Clinic will take part in this study. There are six clinics participating. These six clinics are located in Birmingham, Houston, Boston, San Diego, Miami, and Seattle.

Explanation of Procedures

If you enter the study, you will be offered a computer-based intervention (CBI). The CBI will consist of questions, motivational messages, ideas, and tips for medication adherence, clinic attendance, and risk behavior. You will be asked to complete the CBI at two scheduled appointments, either at primary care visits or other visits to the clinic. Additionally, you may be referred to a Health Coach for one-on-one counseling to address barriers and benefits of improving health. You may have three counseling sessions with the Health Coach. Each CBI session is expected to last about 15 minutes; Health Coach sessions are expected to last about 60 minutes. You will receive a token of appreciation of up to \$10 for participating in a Health Coach counseling session.

If you enroll, you will be asked to provide information about how we can best contact you. With your permission, study staff may get in touch with you by phone, send you e-mail, or regular mail, to schedule counseling sessions, to send reminder notices, or to follow-up with you if you miss a scheduled appointment at the clinic.

For all persons in this study, we will need to access limited HIV medical data (CD4 count, viral load, dates of tests) and clinic attendance data from medical records during the next 24 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 a

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.

Risks and Discomforts

Some people feel that sharing information for research studies is uncomfortable as questions about sexual risk behaviors or medical care may cause you to feel sad, upset, or angry. There may also be risks of inconvenience and possible loss of privacy associated with taking part in a research study. You may choose not to answer any question and to end the sessions at any time for any reason. If you become distressed during the sessions, you will be offered the opportunity to speak with a counselor, social worker, or other appropriate staff member at the Clinic. The things that you talk about and/or your responses to the CBI will not be shared with your medical provider, and your sessions with the Health Coach, if assigned, will be in a private space.

Benefits

There are no direct medical benefits to you by joining this study. Patients who are chosen to meet with the study staff will participate in sessions that discuss barriers and benefits to improved health. The results of this study may help us to improve services given to patients at this clinic.

Alternatives

You have the choice to not take part in this study. If you choose not to take part, your choice will not affect the medical care that you receive at this clinic.

Privacy

All of the information you give us will be kept private to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Centers for Disease Control (CDC) and the Office for Human Research Protections (OHRP).

Please note that your responses, reported information, or discussion topics will only be shared if you report that you were being abused, or that you were seriously considering harming yourself or someone else. In this case, the staff would have to tell someone to protect you or another person from harm.

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 storage device that is protected by a password. All study materials will be stored in a locked file cabinet in locked offices of study personnel.

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

When we write about the results of the 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.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study or if you are not following the study rules.

If you are a UAB student or employee, you may choose not to be in the study or you may withdraw from the study at any time before it is over. This will not affect your class standing, grades, employment or relationship with UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no costs to you for participating in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Token of Appreciation for Participation in Research

You will receive up to \$30 as a token of appreciation for participating in all 3 Health Coach counseling sessions.

Significant New Findings

You will be told by your doctor or study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact the study's Principal Investigator, Michael Mugavero, MD. He will be glad to answer any of your questions. Dr. Mugavero's number is (205)996-5822. Dr. Mugavero may also be reached after hours by paging him at (205)934-3411 (beeper 8458).

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you agree to participate in this study. You may receive a signed or unsigned copy of this document.

Signature of Participant

Date

Signature of Principal Investigator or Person Obtaining Consent

Date

Signature of Witness

Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION
FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant Name: _____ **UAB IRB Protocol Number:** X130715003
Research Protocol: Implementation and Evaluation of a Comprehensive Prevention with Positives Intervention at HIV Clinics **Principal Investigator:** Michael J Mugavero, MD
Sponsor: Centers for Disease Control and Prevention (CDC)

What health information do the researchers want to use? All medical information and personal identifiers, including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____

**UNIVERSITY OF WASHINGTON
CONSENT FORM**

Computer-Based Intervention

Researchers: Shireesha Dhanireddy, MD, Matthew Golden, MD, Heidi Crane, MD; Division of Infectious Disease, Department of Medicine. Phone: 206 744-5103

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Almost half of all people who have been diagnosed with HIV are not receiving regular medical care. Some people miss appointments. Others have big gaps between their visits to the clinic. Often people who feel well or are not taking HIV medicines miss a lot of appointments or don't come to the clinic regularly.

Experts in the U.S. now recommend that doctors give HIV medicines to all their patients with HIV. Those medicines improve the health of people with HIV and make it less likely that people will give HIV to their sex partners.

The purpose of this study is to find out if an intervention that includes counseling using a computer and talking to a health coach can increase the number of patients who regularly take their HIV medicine.

STUDY PROCEDURES

The computer intervention takes about 10-15 minutes. It is meant to encourage people to take their HIV medicines. If you agree to be in the study, the computer will ask you questions about taking HIV medicines and how often you come to the clinic. It will also ask you how often you use condoms when you have sex. We will ask you to do the computer counseling up to two more times when you come back to the clinic for care visits.

RISKS, STRESS, OR DISCOMFORT

Some of the questions that the computer asks you may make you feel uncomfortable. If other people knew your answers, it could damage your reputation.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you decide not to do the computer counseling you can still talk to the health coach who works for the study. The health coach will talk to you about taking HIV medicines and about safe sex. If you choose

not to participate at all in the study, you can still talk to your medical provider and case worker about your medical care, taking HIV medicines and about safe sex. The clinic also sometimes has a health educator who can talk to you.

BENEFITS OF THE STUDY

Participating in the study may help you come to the clinic more often when you need to. It might also help you take your HIV medicines more consistently, and decrease the risks you take with sex. Taking your medicine and using condoms can help improve your health and decrease the risk that you give HIV to someone else.

SOURCE OF FUNDING

This study is funded by the Centers for Disease Control and National Institute of Mental Health.

PRIVACY OF RESEARCH INFORMATION

The study will use information already on file at the clinic if we need to reach you. All of the information you give us during the study will be secure. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. Government or university staff members sometimes review studies to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

You are free to say you don't want to be in the study. You may refuse to answer any study questions. Whether or not you participate in this study the care you receive in the clinic or at Harborview will not be affected. You are free to stop participating in the study at any time.

Printed name of study staff obtaining consent	Signature	Date
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Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date
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When subject is not able to provide informed consent:

Printed name of representative	Signature of representative	Date
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**UNIVERSITY OF WASHINGTON
CONSENT FORM**

Health Coach Counseling

Researchers: Shireesha Dhanireddy, MD, Matthew Golden, MD, Heidi Crane, MD; Division of Infectious Disease, Department of Medicine. Phone: 206 744-5103

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Almost half of all people who have been diagnosed with HIV are not receiving regular medical care. Some people miss appointments. Others have big gaps between their visits to the clinic. Often people who feel well or are not taking HIV medicines miss a lot of appointments or don't come to the clinic regularly.

Experts in the U.S. now recommend that doctors give HIV medicines to all their patients with HIV. Those medicines improve the health of people with HIV and make it less likely that people will give HIV to their sex partners.

The purpose of this study is to find out if an intervention that includes counseling using a computer and talking to a health coach can increase the number of patients who regularly take their HIV medicine.

STUDY PROCEDURES

If you agree to be in this study, you will speak with a Health Coach. The Health Coach will talk to you about taking HIV medicines, regularly coming to the clinic, taking HIV medications, and safe sex.

The health coach may ask to follow-up with you. They may also ask to contact you using text messaging or other forms of communication.

RISKS, STRESS, OR DISCOMFORT

The health coach may ask you questions about sex and drug use that make you feel uncomfortable. If other people heard those conversations or learned what you said it could damage your reputation.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you chose not to be in the study you can talk to your medical providers, case workers or the clinic health educator about your medical care and sexual risks.

BENEFITS OF THE STUDY

Participating in the study may help you come to the clinic more often when you need to. It might also help you take your HIV medicines more consistently, and decrease the risks you take with sex. Taking your medicine and using condoms can help improve your health and decrease the risk that you give HIV to someone else.

SOURCE OF FUNDING

This study is funded by the Centers for Disease Control and National Institute of Mental Health.

PRIVACY OF RESEARCH INFORMATION

The study will use information already on file at the clinic if we need to reach you. All of the information you give us during the study will be secure. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. Government or university staff members sometimes review studies to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

You are free to say you don't want to be in the study. You may refuse to meet with the health coach. Whether or not you participate in this study the care you receive in the clinic or at Harborview will not be affected. You are free to stop participating in the study at any time.

You will receive a \$10.00 token of appreciation when meeting with the health coach.

Printed name of study staff obtaining consent	Signature	Date
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Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date
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University of California, San Diego

University of California, San Diego

Consent to Act as a Research Subject (for Health Coach Counseling)

Comprehensive HIV clinic-based intervention to promote study participants' health and reduce transmission risk

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study.

Dr. Edward Cachay and the Owen Clinic are conducting a research study to find out more about comprehensive HIV-clinic based intervention to promote study participants' health and reduce transmission risk. In this study, participants will complete a computer-based education intervention (CBI) and receive individual counseling sessions with a health coach. The study is being conducted to learn whether the CBI and health coaching will reduce the amount of HIV in your body by improving your adherence to antiretroviral medications. Your participation in this study is entirely voluntary. You have been asked to participate in this study because you represent people who may benefit from such research interventions. The computer-based intervention (CBI) involves answering questions about how you are doing with taking your HIV medications (if you take these) and how you feel about coming to the clinic to receive your medical care. There are also questions about recent sexual behavior. You will receive these research interventions at the Owen Clinic when you come for regularly scheduled medical appointments and possibly at other times if convenient for you. Your responses will identify areas in which your health coach can help you through personal motivational sessions. There will be approximately 250 participants who will complete the health coach counseling sessions at this site.

This study is being conducted by the University of California, San Diego. This study is funded by the Centers for Disease Control and Prevention (CDC) and the National Institute of Mental Health (NIMH).

Why is this study being done?

The purpose of the study is to learn whether research interventions offered to study participants will help improve their health by lowering the amount of HIV in their body. The research interventions will focus on the importance of following your doctor's recommendations about taking HIV medications, the importance of coming regularly for medical care, and the importance of safer sex practices if needed.

What will happen to you in this study and which procedures are standard of care and which are experimental?

Any study participant who receives clinical services at the UCSD Owen Clinic completes quarterly a screening inventory and primary care providers receive a one page summary of the study subject's screener responses. Your medical provider receives the screener summary as a printed page that highlights areas that your medical provider uses to improve your health. This screener information is used solely for clinical care; the information will not be transmitted to CDC or used for research purposes. With the availability of this research intervention program, providers will be asked to inform all study participants about the availability of a computer-based intervention classes that may benefit them. Study participants however may refuse to do the computer classes without jeopardizing their care at the Owen clinic or medical center. Providers have the discretion to request that a study participant see the health coach (described below) for

one-on-one counseling before the study participant does the computer classes.

If you join the study, you will be offered private one-on-one counseling from a trained health coach at this clinic in conjunction with your routine clinic appointment or at a different time if it is more convenient for you. Before the counseling session you will be asked to do a 10 minute computer-based intervention in a private room. You can still participate in the study even if you have not completed prior computer-based intervention. During the computer-based intervention, you will be asked questions about how you are doing with taking your HIV medications (if you take these), and about how you feel about coming to the clinic for HIV medical care. There are also questions about your recent sexual behavior. Your answers will be private. Your answers will be identified by a code number only. Your name will not be included. None of the doctors, nurses, or clinic staff will see your answers. The counselor will not see your answers to the computer questions. You will receive a summary list of some tips that might benefit you. You will be asked to do the short CBI a few months later when you are at the clinic.

The health coach counseling session will focus on ways to help study participants take HIV medications, come regularly to clinic for HIV medical care, and have safer sex as needed. A counseling session will last about 60 minutes and study participants will have 3 counseling sessions on separate days. After the third counseling session, you will be asked to privately answer a few questions on a computer.

The counselor will ask you to provide information about how he/she can contact you to see how you are doing. With your approval, the counselor may call you on the phone; send you letters, email or regular mail, or text you, whatever work best for you. Your private medical information will not be written in any letters or left on voice mail. The counselor will work with you to determine which methods of contact will be most helpful for you and also protect your privacy. For all study participants in this study, we will need to get limited HIV medical data (CD4 count, viral load, dates of tests) and clinic attendance data from your medical records at this clinic. You will not have any blood drawn as part of this study. We will use lab tests that are part of your regular medical care at this clinic. The data will be used in the analysis of this study. Only a code number, not your name or your medical record number, will be used to identify the data.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

This study will last for approximately 18 months. Each computer-based intervention will take approximately 10 minutes. The total time commitment for each counseling session with the health coach is 60 minutes and you will have 3 counseling sessions with the health coach. Your total time commitment will be a minimum of 3 hours and 20 minutes.

What risks are associated with this study?

Participation in this study may involve some unforeseen risks or discomforts. These include the following: 1. A few of the computer questions ask about sexual behavior may make you feel uncomfortable. None of your answers to the computer-based education intervention (CBI) questions will be seen by your medical providers or by any clinic staff. All your answers including those disclosing sexual behaviors will be sent to the CDC using a computer generated code number that will not link you in any manner to your name or identify you in any other way. You may refuse to answer any of the computer questions. 2. Information you share with a study counselor will be kept private and will not be shared with any other persons. 3. The research staff will only know the date and time of a counseling session. 4. Your doctor will see a brief note in your electronic medical record that documents the counseling session. This note will only

describe general domains that you are working on with your health coach but there will not be specific details of what you discuss with your health coach.

What are the alternatives to participating in this study?

The alternatives to participation in this study are that the study participant may receive the same interventions offered to study participants, but without being formally part of the study and having to have their information sent to the CDC.

What benefits can be reasonably expected?

There may or may not be any direct benefit to you from these research interventions. The investigator, however, may learn more about a comprehensive HIV clinic-based intervention to promote study participants' health and reduce transmission risk.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?

Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be requested to inform the study coordinator or health coach.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?

You may be withdrawn from the study for the following reasons: 1) Your doctor believes it is your best medical interest. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?

We will provide you with a \$10.00 token of appreciation when you come for a one-on-one counseling session with the health coach. There will be no other reimbursement.

Are there any costs associated with participating in this study?

There are no costs to you for participating in this research study.

What if you are injured as a direct result of being in this study?

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the UCSD Human Research Protections Program Office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject, or to report research-related problems.

What about your privacy

All of the information you give us will be kept private to the extent allowed by law. Only a code number, not your name, will be used in the computer survey and on your study data. Your answers to the computer questions will not be stored on the computer or on any storage device at this clinic. Instead, your answers are immediately sent to a highly secure storage device at the CDC. The data sent to the CDC will not include your name or any other way for the CDC to identify you. Only your code number will be sent with your data to the CDC. Any contact information (like your phone number or address) that you give to the counselor will not be stored on any study computer

or storage device. This information is usually part of your electronic medical records and if it is different from what is documented, it will be updated accordingly to facilitate your medical care.

When the study is over, information that can potentially link you as a participant in the study will be destroyed. There will be no way to link you personally to your computer survey or to other study data.

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.

Who can you call if you have questions?

_____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Cachay at (619) 543-3995.

You may call the Human Subjects Research Protections Program Office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent

You have received a copy of this consent document and a copy of the “Experimental Subject’s Bill of Rights” to keep.

You agree to participate.

Subject’s Signature Date

Witness’s Signature and Date