HOPS SITE 1012
Dupont Circle Physicians Group

- This site defers to the CDC IRB, and therefore does not have a yearly local IRB approval
- English language consent

OMB Control Number: 0920-1080
Expiration date: 02/29/2024

HOPS Informed Consent Forms

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

The following information is being presented to help you decide whether or not you want to participate in a research study. Please read it carefully. If there is anything you do not understand, ask the doctor.

Study Title:"The HIV Outpatient Study (HOPS)"

Study Site: Dupont Circle Physicians Group

Principal Investigator: Jessicamarie Fox, NP-C

Address: 1145 19th St NW, Washington, DC 20036

Phone: (202) 745-0201

Study Sponsor: Centers for Disease Control and Prevention (CDC) and Cerner Corporation

Study funded by: Centers for Disease Control and Prevention (CDC)

PURPOSE: You are being invited to participate in this research study because you are a patient at our clinic and you are HIV-positive. Our clinic works collaboratively with the Centers for Disease Control and Prevention (CDC) and Cerner Corporation. Cerner collects information on patients with HIV infection from medical clinics in the United States for a research study to better understand HIV disease and treatments. Data gathered by Cerner are shared with the CDC. The data may also be used for other purposes permitted by law, including comparative data analysis and the development, marketing and distribution of products and services.

We are asking you to allow us to use information gathered as a result of your treatment at this clinic. Your information will be included in the Cerner's database with data from over 9,000 HIV-positive patients seen at several clinics around the country. This database has already been existence for many years.

PROCEDURE: Data for this project will be gathered from your medical record; this will not require any effort from you. The database includes demographic information, diagnoses, laboratory results, symptoms, treatments, and hospitalizations. Information in the database is handled with the same strict privacy as your medical record.

In addition we may occasionally ask you to participate in surveys or questionnaires on various topics. These may include personal questions about sex, drug use, medication adherence, or other topics. These surveys or questionnaires may be done on paper, by computer, or by an automated telephone system. You may refuse to participate in these special studies and still be in the main study.

This study will not require extra office visits or extra lab tests. It will cost you nothing to be in this study.

RISKS: There are no known health risks to you from participating in this study.
There is a risk of loss of privacy, meaning that information collected about you could become known to others outside of the study. To minimize the risk of this happening, your data in the database is identified only by a code number.

The additional surveys or questionnaires that you may be asked to participate in may include questions about sexual practices, illegal drug use, or similar topics. Although these surveys are private, questions about these topics may cause some discomfort or anxiety.

BENEFITS: There is no direct benefit to you from participating in this study. The information gathered in this study, however, may result in a better understanding of HIV disease and treatments, which may ultimately benefit persons with HIV infection.

Privacy: Your personal identifying information (including your name, date of birth, and possibly your medical record number) will be entered and kept in a private and secure database, separately from your medical information. Your personal identifying information cannot be seen by anyone outside of this clinic. Cerner and CDC study staff will see your medical information in the database only with your secure HOPS study participant number, not your name.

Your medical records and the consent form you sign may be inspected by authorized research investigators or the CDC to make sure the study follows federal and state regulations. From time to time, Cerner or CDC staff may review your medical records and survey data to check that your information in the database is correct. Because of this need, we cannot guarantee absolute privacy. However, CDC and Cerner staff are held to the same rules of privacy as office and study staff.

If the results of this research are published in a medical journal or presented at a conference they will not include your name or any other information that may identify you.

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit or as evidence. This protection applies to requests from federal, state or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things you need to know. The Certificate DOES NOT protect your information if federal, state or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the

research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as data collected from your medical records for this research.

PAYMENT FOR STUDY PARTICIPATION: You will not be paid to participate in this study.

VOLUNTEERING TO BE PART OF THIS RESEARCH STUDY: Your participation in this study is voluntary. You may refuse to participate or you may quit at any time. If you decide to stop taking part in this study, tell the study doctor and your data will stop being added to the study database. Any of your information already in the database at the time you quit the study may be still used for research.

If you stop participating in this study, this will not affect your medical care, benefits to which you are otherwise entitled, or ability to take part in future research studies.

TERMINATION: We do not know when this study will end. It will go on until it is stopped for some reason, or until funds are gone. The investigator or the sponsor may terminate your participation in this study without your consent**.**

QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Jessicamarie Fox, Investigator, at (202) 745-0201.

If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the CDC's Human Research Protection at 1-800-584-8814.

CONSENT STATEMENT

By signing this form, I confirm that

- I have fully read (or someone has read and explained to me) this informed consent form describing a research study.
- I was given the opportunity ask questions and my questions have been answered to my satisfaction.
- I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form.
- I understand that I am not giving up any of my legal rights.
- I have been offered a copy of this informed consent form, which is mine to keep.

*_____ _____ _____

Signature of Participant Printed Name of Participant Date

_____	_____	_____
Signature of Witness (if appropriate)	Printed Name of Witness	Date

INVESTIGATOR STATEMENT:

The subject signing this consent form has had the study fully and carefully explained to him or her. I hereby certify that, to the best of my knowledge, the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study

_____	_____	_____
Signature of Investigator	Printed Name of Investigator	Date

_____	_____	_____
Signature of Person Obtaining Consent If Other than Investigator	Printed Name	Date

The research project/study and informed consent form were reviewed and approved by the CDC Human Research Protection Institutional Review Board. The board may be contacted at 1-800-584-8814.

HOPS SITE 1021/1025
Vivent Health

- English language consent

Form Approved
OMB No. 0920-1080
Expiration Date: 02/29/2024

VIVENT HEALTH
CYNTHIA S. FIRNHABER, MD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

The following information is being presented to help you decide whether or not you want to participate in a research study. Please read it carefully. If there is anything you do not understand, ask the doctor.

Study Title: The HIV Outpatient Study (HOPS)

Study Site: Vivent Health

Principal Investigator: Cynthia S. Firnhaber, MD

Address: 5250 Leetsdale Drive, Suite #300, Denver, Colorado 80246

Phone: (303) 393-8050

Study Sponsor: Centers for Disease Control and Prevention & Cerner Corporation

PURPOSE: Our office works with Cerner Corporation. Cerner Corporation collects and shares information on the course of and changes in the disease, symptoms, and treatments of HIV infection. Data gathered by Cerner Corporation will be shared with the Centers for Disease Control and Prevention (CDC). Your participation in this study is voluntary and you may decide to withdraw at any time.

We are asking you to allow us to use information given by you or gathered as a result of your treatment at this clinic. This data will be used to create a database of clinical findings. The data may also be used for other purposes permitted by law, including without limitation, comparative data analysis and the development, marketing and distribution of other products and services. Your data will be grouped with data gathered on over 10,000 patients around the country. This database will span many years of treatment.

PROCEDURE: Data for Cerner Corporation is gathered from your medical record, and will not require any effort from you. The database includes demographic information, diagnoses, laboratory results, symptoms, treatments, and hospitalizations. Data in the database is handled with the same strict confidentiality as your medical record. There is no end date for this study. It will go on until it is stopped for some reason, or until funds are gone.

In addition, we may occasionally ask you to participate in surveys or questionnaires on various topics. These may include personal questions about sex, drug use, medication adherence, or other topics. These surveys or questionnaires may be done on paper, by

computer, or by an automated telephone system. You may refuse to participate in these special studies and still be in the main study.

This study will not require extra office visits or extra lab tests. It will cost you nothing to be in this study.

RISKS: There are no known health risks to you from participating in this study.

There is a risk of loss of confidentiality, meaning that information collected about you could become known to others outside of the study. To minimize the risk of this happening, your data in the database is identified only by a code number.

The additional surveys or questionnaires that you may be asked to participate in may include questions about sexual practices, illegal drug use, or similar topics. Although these surveys are confidential, questions about these topics may cause some discomfort or anxiety.

BENEFITS: There may be no direct benefit to you from your participation in this study. The information gathered in this study, however, may result in a better understanding of HIV disease and treatments, which may ultimately benefit persons with HIV infection.

FINANCIAL RESPONSIBILITY: This study will not require extra clinic visits or extra lab tests. It will cost you nothing to be in this study. You will not receive extra care if you agree to be in this study, and the cost of your health care will not change.

COMPENSATION: There will be no compensation to you for participation in this study.

ALTERNATIVES: The only other option to being in this study is to not be in this study.

CONFIDENTIALITY: Your personal identifying information (including your name, date of birth, and possibly your medical record number) will be entered and kept in a confidential and secure database, separately from your medical information. Your personal identifying information cannot be seen by anyone outside of this clinic. Cerner and CDC study staff will see your medical information in the database only with your secure HOPS study participant number, not your name.

Your medical records and the consent form you sign may be inspected by authorized research investigators or the CDC to make sure the study follows federal and state regulations. From time to time, Cerner or CDC staff may review your medical records and survey data to check that your information in the database is correct. Because of this need, we cannot guarantee absolute confidentiality. However, CDC and Cerner staff are held to the same rules of confidentiality as office and study staff.

If the results of this research are published in a medical journal or presented at a conference, they will not include your name or any other information that may identify you.

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit or as evidence. This protection applies to requests from federal, state or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things you need to know. The Certificate DOES NOT protect your information if federal, state or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as data collected from your medical records for this research.

COMPENSATION FOR INJURY: If you are harmed as a result of joining this study, there are no plans to compensate you or pay for medical costs not covered by your insurance plan. Neither the CDC, Cerner Corporation, nor Vivent Health will assume any such responsibility. The above does not prevent you from seeking such compensation.

PATIENT'S RIGHTS: As a research study patient, you have the right to ask questions. You should not agree to be in this study until all your questions have been answered. You have the right to withdraw from this study at any time. If you chose to withdraw from this study, your care will not change. If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the CDC's Human Research Protection at 1-800-584-8814.

If you have any questions or problems related to this research study, or if you wish to withdraw from this study, you may call Dr. Cynthia (Cindy) Firnhaber at 303-393-8050.

CONSENT:

I, _____, hereby authorize Dr._____ and Cerner Corporation to use any information given by me, or by my doctors as a result of my treatment. I know that this information will be used by members of Cerner Corporation and the Centers for Disease Control and Prevention for studies on the causes of illness, treatments, and outcomes of patients with HIV.

I have been given the chance to ask questions, and am satisfied with the answers I have received. I know that I will be given a copy of this consent form. I know that I may withdraw from this study at any time, and that withdrawing will not affect my treatment. I have been given the name and number of a contact person for questions, concerns, or to call if I wish to withdraw.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a patient or a participant in a research study.

Patient Name	Patient Signature	Date
Name of Witness (if appropriate)	Witness Signature	Date

INVESTIGATOR STATEMENT:
The subject signing this consent form has had the study fully and carefully explained to him or her. I hereby certify that, to the best of my knowledge, the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study.

Signature of Investigator	Printed Name	Date
Signature of Person Obtaining Consent if Other than Investigator	Printed Name	Date

HOPS SITE 1040
Northwestern University

- English language consent

Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above

OMB Control Number: 0920-1080
Expiration Date: 09/29/2024

Title of Research Study: HIV Outpatient Study (HOPS)

Investigator: Frank Palella, MD

Supported By: This research is supported by Cerner Corporation and Centers for Disease Control (CDC)

Financial Interest Disclosure:

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are HIV positive and will be receiving treatment at our clinic for your disease.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this research study is to collect and share information on the course and changes in the diseases, symptoms, and treatments of HIV infection. Data gathered by Cerner will be shared with the Centers for Disease Control and Prevention (CDC). This database will be used for research to better understand HIV and to improve treatment of HIV.

You are being asked to allow us to use the information given by you or gathered as a result of your treatment at this clinic. This data will be used to create a database of clinical findings. This database will span many years of treatment.

Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above

How long will the research last and what will I need to do?
We expect that you will be in this research study for as long as your receive treatment at this clinic.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
Your participation in this study does not involve any physical risk to you.

Will being in this study help me anyway?
There may be no direct benefit to you by your participation in this research study. We cannot promise any benefits to you or others from you taking part in this research. However, possible benefits include helping people who research HIV disease to better understand the disease.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which are entitled.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 926-8358.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above

How many people will be studied?
Your data will be grouped with data gathered on over 10,000 subjects around the country.

What happens if I say "Yes, I want to be in this research"?
Data for Cerner is gathered from your medical record, and will not require any effort from you.
Data in the database is handled with the same strict confidentiality as your medical record. There is no end date for this study. During your participation in this study, you may be approached to participate in special studies through which extra data will be gathered by surveys on topics that might be of interest at that time. Some of these surveys could ask personal questions about sex, drug use, payment for medical care, or medication adherence. You will not have to be in any of the extra studies just because you are a part of this study. You may refuse to participate in these special studies and still be in the main study.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Detailed Risks: Is there any way being in this study could be bad for me?
This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: "What happens to the information collected for the research?"

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Cerner Corporation, the Centers for Disease Control (CDC), the IRB and other representatives of this institution.

Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above

This data may be used for other purposes permitted by law, including without limitations, comparative data analysis and the development, marketing and distribution of other products and services. No personal identifying information will be collected such as name, address, phone number, medical record number, or social security number for Cerner Corporation or the CDC. Allowing your data to be used for these purposes is not considered optional, unless you decline to participate in the study.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

HIPAA Authorization
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- HIV Testing Results
- Substance abuse information, such as alcohol and drug use
- Mental Health information, such as any diagnosis listed in your medical record, as well as treatment on antidepressants, etc.

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan Ability Lab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized **members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research and members of the Institutional Review Board.**
- Clinical affiliates, including but not limited to the Shirley Ryan Ability Lab (SRALAB), **Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.**
- Other University research centers and University contractors who are also working on the study**.**
- Study monitors and auditors who make sure that the study is being done properly.
- Cerner Corporation and CDC, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the receivers of the information except in precise situations allowed by law.

Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of research study.

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to

PI's Name: Frank J. Palella, Jr., MD
Institution: Northwestern University
Division of Infectious Disease
Address: 645 N. Michigan Ave., Suite 900, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

HOPS SITE 1041
SUNY-Stonybrook

- English language consent

OMB Control Number:0920-1080
Expiration date: 02/29/2024

Stony Brook University

INFORMED RESEARCH CONSENT FORM

Project Title: HIV Outpatient Study
Principal Investigator: Jack Fuhrer, MD
Department: Infectious Disease

You are being asked to be a volunteer in a research study.

You are being asked to participate in a study entitled "HIV Outpatient Study". Jack Fuhrer, MD is the principal investigator. Together with Cerner Corporation, we collect and share information on the course of, and changes in the diseases, symptoms, and treatments of HIV infection. Data gathered by the Cerner Corporation will be shared with the Centers for Disease Control And Prevention.

PURPOSE

The purpose of this study is:

You are being invited to participate in this research study because you are a patient at our clinic and you are HIV positive. Our clinic works collaboratively with the Centers for Disease Control and Prevention (CDC) and Cerner Corporation. Cerner collects information on patients with HIV infection from medical clinics in the United States for a research study to better understand HIV disease and treatments. Data gathered by Cerner is shared with the CDC. The data may also be used for other purposes permitted by law, including comparative data analysis and the development, marketing, and distribution of products and services.
We are asking you to allow us to use information gathered as a result of your treatment at this clinic. Your information will be included in Cerner's database with data from over 10,000 HIV positive patients seen at several clinics around the country. This database has already been in existence for many years.

PROCEDURES

If you decide to be in this study, your part will involve:

Data for the HIV Outpatient Study is gathered from your medical record, and will not require any effort from you. The database includes demographic

information, diagnoses, laboratory results, symptoms, treatments, and hospitalizations. Information in the database is handled with the same strict confidentiality as your medical record. In addition, we may occasionally ask you to participate in surveys or questionnaires on various topics. These may include personal questions about sex, drug use, medication adherence, or other topics. These surveys or questionnaires may be done on paper, by computer, or by automated telephone systems. You may refuse to participate in these special studies and still be in the main study. This will not require extra office visits or extra lab tests. It will cost you nothing to be in this study.

RISKS/DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

There are no known health risks to you from participating in this study.

There is a risk of loss of confidentiality, meaning that information collected about you could become known to others outside the study. To minimize the risk of this happening, your data in the data base will be identified only by a code number. The additional surveys or questionnaires that you may be asked to participate in, may include questions about sexual practices, illegal drug use, or similar topics. Although these surveys are confidential, questions about these topics may cause some discomfort or anxiety.

BENEFITS

There is no direct benefit to you for participating in this study.

The information gathered in this study, however, may result in a better understanding of HIV disease and treatments, which may ultimately benefit persons with HIV infection. You will not receive extra care if you agree to be in this study, and the cost of your healthcare will not change.

PAYMENT TO YOU

You will not be paid for participating in this study. If any products or services are developed from study data, you will not receive any share of resulting profits.

PAYMENT TO THE INSTITUTION

This project is funded, in part, by a grant or contract from the Cerner Corporation and the Centers for Disease Control and Prevention (CDC) to the Research Foundation of Stony Brook University, in support of the Investigators' work on this study.

CONFIDENTIALITY

Protecting the Privacy of Your Health Information:

We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, the sponsor of the study (Cerner Corporation and Centers for Disease Control and Prevention (CDC)), Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices. However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, the sponsor of this study, those who work for the sponsor, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and certain federal offices) as well as:

- your insurance company
- your private doctor

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission. For example, the sponsor of this study does not have to make the same promise under the law to protect your health data.

Some of the health information we get from you in this study cannot be shared with you until the end of the study.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Dr Jack Fuhrer. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

COSTS TO YOU

There are no costs to you for your participation in this study.

ALTERNATIVES

Your alternative to being in this study is to simply not participate.

REMOVAL FROM STUDY

We do not know when this study will end. It will go on until it is stopped. The investigator or the sponsor may terminate your participation in this study without your consent.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty. If you stop participating in this study, this will not affect your medical care, benefits to which you are otherwise entitled, or ability to take part in future research studies.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. Jack Fuhrer at telephone # (631)-444-1667.
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Lu-Ann Kozlowski,BSN,RN at (631)-632-9036 or by e-mail, lu-ann.kozlowski@stonybrook.edu.
- Visit Stony Brook University's Community Outreach page, http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Subject Name (Printed)	Subject Signature	/ / Date
Name of Person Obtaining Consent (Printed)	Signature of Person Obtaining Consent	/ / Date

HOPS SITE 1057
Temple University

- English language consent
- Spanish language consent

OMB Control Number: 0920-1080 expiration date: 02/29/2024

Temple IRB Approved

02/28/2023

Title of research study: #3156 HIV Outpatient Study (HOPS)

Investigator and Department: Ellen M. Tedaldi, M.D., General Internal Medicine

Why you are being invited to take part in a research study:

We invite you to take part in a research study because you have HIV infection and we are collecting information about the course of and changes in treatments, diseases and outcomes of persons living with HIV in the United States. We are working with a health database that is run by Cerner Corporation in cooperation with the Centers for Disease Control and Prevention (CDC). The database will have the same information gathered in 8 other clinics around the country.

What you should know about a research study:

- Someone will explain this research study to you.
- You volunteer to be in a research study.
- Whether you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide, it will not affect your care.
- Feel free to ask all the questions you want before and after you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team at ***: Dr. Ellen Tedaldi, MD, General Internal Medicine, 1316 W. Ontario Street, Philadelphia, PA 19140, Phone: 215-707-1800***

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at ***(215) 707-3390 or e-mail them at: irb@temple.edu*** for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
  - You cannot reach the research team.
  - You want to talk to someone besides the research team.

  - You have questions about your rights as a research subject.
  - You want to get information or provide input about this research.

Why are we doing this research?

The information in the database helps doctors, researchers and other persons caring for persons with HIV infection to know about the latest treatments, complications, conditions and outcomes in a diverse group of patients in the United States.

How long will the research last?

We expect that you will be in this research study for years as long as the database collection is funded and approved to continue. The study began in 1994 and has been funded every year since then.

How many people will be studied?

We expect about 3000 people here at Temple will be in this research study out of 10,000 active people in the entire study nationally.

What happens if I say yes, I want to be in this research?

Information for the database is gathered from your medical record, and will not require any effort by you. Your health care provider, the Cerner Corporation, and the CDC, will analyze data about your symptoms, treatments, diagnoses, hospitalizations and medications.

You may be asked to participate in a computerized survey that will collect information about your habits including tobacco, alcohol or drug use as well as sexual practices. This information is anonymous and is not available to your provider. This is a Telephone Audio Computer Assisted Clinical Interview (T-ACASI) and is not part of your medical record or regular database information

What are my responsibilities if I take part in this research?

You have no responsibilities if you agree to take part. All the information about you will be collected if you continue to receive care at Temple Hospital and the ambulatory medical practices.

If you agree to participate in the T-ACASI survey, you will be asked to complete the survey on a phone in the medical office by a research assistant or you can complete the survey on your own phone. You will receive only an identification number and nothing with you name or personal health information

What happens if I say no, I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. It will in no way affect your relationship with the study doctor.

There are no known risks involved in this study. This study will not require extra clinic visits or extra lab tests. You will have to pay nothing to be in the study. Sometimes, extra data will be gathered for a special study through surveys on a topic that might include questions about sex, drug use, or medication adherence. You will not have to be in any of the extra studies just because you are part of this study. You may refuse to participate in these special studies and still be in the main study.

What happens if I say yes, but I change my mind later?

You agree to take part in the research now and if you stop at any time, it will not be held against you. Again, it will in no way affect your relationship with the study doctor.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me?

There is no way that this study could be bad for you as there is no direct treatment while being enrolled. The study is collecting information only with your identity recorded as a study number only.

Will being in this study help me in any way?

You gain nothing from being in this study except to aid research in HIV disease and better understand the disease. You will not receive extra care if you agree to be in this study, and the cost of your health care will not change.

What happens to the information we collect?

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. For example, though the study team has put in safeguards to protect your information, there is always a potential risk of loss of confidentiality.

Organizations that may inspect and copy your information include the IRB, Temple University, Temple University Health System, Inc. and its affiliates, and other representatives of these organizations, and the Office of Human Research Protections. In addition the Center for Disease Control and Prevention and Cerner Corporation will be able to review the data with no personal identifiers attached. The monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to the portion of your medical records which are related to this research study for verification of the research procedures and date. You will need to sign a separate “Authorization to use and disclose your protected health information” to be a part of this research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Federal law provides additional protections of your personal information. These are described in an attached Authorization document referred to above.

Can I be removed from the research without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include that you no longer receive care at Temple Hospital or the ambulatory practices. The sponsor can also end the research study early.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you sustain an injury as a result of your participation in this research study, the physician's fees and medical expenses that result will be billed to your insurance company or you in the usual manner. Other financial compensation (such as lost wages or pain and suffering) for such injuries is not routinely available. By signing this consent form, you are not waiving any of the legal rights that you otherwise would have as a participant in a research study. If you have questions about the study or a research-related injury, please contact **Dr. Ellen M. Tedaldi during regular hours and at (215) 707-1800** after hours and on weekends and holidays.

Stipend/Reimbursement

If you agree to take part in this research study, there is no payment to you.

Participating in Future Research Studies

We may want to contact you in the future to see if you would be interested in participating in another research study and/or to obtain additional information related to your participation in this study. Please indicate by initialing on the line in the next paragraph below if you are willing to be contacted. Please know that you can amend your answer below at any time without prejudice to you or your relationship with the study, Temple University, or the Study doctor and team.

Yes, I agree to be contacted about future research studies. ____

No, I do not want to be contacted about future research studies. ____

Yes, I agree to be contacted to obtain additional information related to my participation in this study. ____

No, I do not want to be contacted to obtain additional information related to my participation in this study. ____

Signature Block for Adult Subject Capable of Consent

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Signature Block for Adult Subject Unable to Consent

Your signature documents your permission for the individual named below to take part in this research.

Printed name of subject	
Signature of legally authorized representative	Date
Printed name of legally authorized representative	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Assnt

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

HOPS SITE 2003
University of Illinois-Chicago (UIC)

- English language main consent
- English language consent amendment
- English language consent for T-ACASI behavioral survey

- Spanish language main consent
- Spanish language consent amendment
- Spanish language consent for T-ACASI behavioral survey

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

University of Illinois at Chicago
Authorization To Use And Disclose Health Information For Research
"CDC HIV Outpatient Study Database"

You are being asked to permit Dr Richard M. Novak of the Department of Infectious Diseases in the College of Medicine and their staff to use and disclose protected health information (PHI) that identifies you for the research purposes described below. You are also being asked to permit your doctors and other health care providers to disclose PHI to these Researchers for the purposes described below. The privacy law [45 CFR Parts 160 and 164], Health Insurance Portability and Accountability Act (HIPAA) provides additional protections for PHI. You must sign this authorization if you wish to allow your PHI to be used or disclosed for this research.

Description of protected health information to be used and disclosed

The protected health information that may be used and disclosed includes all information collected during the research described in the Consent for Participation in Research entitled CDC HIV Outpatient Study Database;

The protected health information that may be used and disclosed includes all protected health information in your medical records that is related to the research including illnesses and hospitalizations that occur while you are participating in the research, as described in the Consent for Participation in Research entitled CDC HIV Outpatient Study Database. This health information includes information contained in your medical chart from all clinic visits and hospitalizations, including demographic information such as your date of birth, age, sex, race; blood test results, x-ray and other diagnostic test results, results of physical exams and symptoms you describe at visits, medical and medication histories.

The protected health information that may be used and disclosed includes the information as described above, which is collected and maintained by your physicians and other healthcare providers which are identified below: Physicians and their staff at UIC.

Research use of your protected health information

- The Researchers can use and share your protected health information to conduct the research;
- The Researchers can disclose your protected health information to the sponsor of the research, Cerner Corporation, as required for the research and if further information is needed to confirm the research;

- The Researchers can disclose your protected health information to other collaborators of the research study: Centers for Disease Control (CDC);
- The Researchers can disclose your protected health information to representatives of government agencies (i.e., Food and Drug Administration) where required by law; and
- The Researchers can disclose your protected health information to the University of Illinois Medical Center at Chicago and University of Illinois at Chicago representatives including the Institutional Review Board.
- Once the Researchers disclose your information to anyone outside of the study, it may be re-disclosed and may no longer be protected by this Authorization and the federal privacy regulations.

Protection of your health information

The Researchers and Cerner Corporation agree to protect your health information by using and disclosing it only as permitted by you in this Authorization or as is directed by state and federal law. Further, no publication about the research will reveal your identity without your express written permission. These limitations continue even if you decide to revoke (take back) this Authorization.

Removal of your identifying information (De-Identification)

Once the information that identifies you is removed, the information that remains is no longer subject to this Authorization or to HIPAA. The remaining information may be used and disclosed by the Researchers as permitted by law and may be used and disclosed for other research purposes.

Access to your protected health information collected in this research

During the time you are partidpating tn the researctt, you will not he allowed to see information collected as part of the research study. Once the study is over, you will have the right to access the information again.

Inclusion of your protected health information in a database or data repository

1'ffl P'iffl-=m-nlm ffl'1i ,_.:;;;;;;;;;;;;.:.:.;;;.;;.,, rn,,, ':;....;. fra11nrtrr,>;__, ch'r:,;.,.i..part of a database or data repository and, therefore, this Authorization will not expire unless you revoke (take back) your Authorization.

Your options

You do not have to sign this Authorization, but if you do not, you will not be allowed to participate in this research study. However, if you decide not to sign this authorization it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Expiration of Authorization

ihis Authorization does not have an expiration date, but can be terminated if you decide to withdraw your permission.

Withdrawal or removal from the study

You may change your mind and revoke this Authorization at any time. To revoke this Authorization, you must write to: Dr. Richard Novak, M.D. UIC College of Medicine, Department of Infectious Diseases (m/c 735) 808 S. Wood Street Rm 886, Chicago, IL 60612. However, if you revoke this Authorization, you may no longer be allowed to continue participation in the research study. Furthermore, even if you revoke this Authorization, the Researchers may still use and disclose health information they already have obtained as necessary to maintain the reliability of the research and to report any adverse effects (bad events) that may have happened to you.

Contact information for questions about my rights under HIPAA

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois at Chicago Privacy Officer at Ph: (312) 996-2271.

If you have not already received a copy of the Notice of Privacy Practices, you should request one. You will be given a copy of this Authorization after it has been signed to keep for your records.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I authorize the use and disclosure of my protected health information for this research.

_____ _____

Signature of Subject Date

_____

Printed Name of Subject

_____ _____

Signature of Witness Date (must be same as Subject's)

_____

Printed name of Witness

Describe why a witness signature is required and the relationship to the Subject.

_____

_____

_____

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

University of Illinois at Chicago
Consent for Inclusion in the CDC HIV Outpatient Study Database

Why am I being asked?

You are being asked to allow information about your treatment for HIV at the University of Illinois at Chicago (UIC) Medical Center to be included in a national database that already includes data from more than seventeen medical centers and thousands of patients with HIV. This study is conducted by Dr. Richard Novak at UIC and Cerner Corporation in Vienna, Virginia. All patients receiving care at the UIC Medical Center clinics are being asked permission to include their medical information in the database. We ask that you read this form and ask any questions you may have before agreeing to be in the research.

Your decision to allow your information to be included in the database is voluntary. Your decision will not affect the care you receive at FCID, nor will it affect future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Why is this research being done?

This database has been created to monitor trends in demographics, symptoms, diagnoses, treatments, and disease outcomes in HIV-positive outpatients in clinics across the United States. This database will combine your information with information from other HIV patients in different parts of the United States to help your physician learn more about conditions associated with HIV infections. By combining information from many different patients, it is possible to learn more about unusual events and to compare the effects of different treatments. The database can be used to determine how well various treatments are tolerated or taken. It can also be used to determine what effect a treatment has on the risk of other infections or hospitalizations, etc. Various investigators, organizations or companies interested in improving treatment of HIV may use this information to develop new treatment strategies for HIV infection. The data may also be used for other purposes permitted by law, including without limitation, comparative data analysis and the development, marketing and distribution of other products and services.

How will the data be collected?

A unique study identification number will be created for you after your visit today. After your first clinic the study data collector will collect demographic information, including your age, sex, ethnicity, and HIV risk behaviors from your chart. Information about your symptoms, diagnosed conditions, medications, and laboratory results will also be collected from your chart after each of your clinic visits. If you are hospitalized, that information will also be entered into the database. If you are already a patient at UIC Medical Center, the data collector will enter information for all you clinic visits since you became a patient at UIC Medical Center.

From time to time, you may be asked to complete a voluntary survey or questionnaire that asks questions about your demographic information (such as age, race or ethnicity), sexual activities, drug use and medication adherence. These surveys or questionnaires will be done either by paper form or telephone at the same time as one of your scheduled clinic visits. You may refuse to participate in these surveys or questionnaires and still be part of the main study.

What are the potential risks and discomforts?

There is a risk of loss of confidentiality, meaning that information collected about you could become known by others outside of the research. To keep this from happening, the information taken from your medical records and information you provide in surveys or questionnaires will be coded with a unique study identification number.

No additional medical tests will be performed and you will not be treated any differently as a result of you information being included in the database.

Are there benefits to taking part in the research?

While the national database may not benefit you directly, information gathered from the database may permit a better understanding of the risks and benefits of the various treatments for HIV. This could eventually benefit a number of persons with HIV infections, including you. Having your clinical information in an organized database may also benefit you by allowing your doctor to view all of your records in one place in a neatly organized manner. Currently, the database used by UIC only includes information from the past three years.

What about privacy and confidentiality?

At no time will anyone outside of UIC be able to identify you or your information through this database. All information will be entered into the database under your unique study number. The only people who have access to the file that can link you to your study identification numberwill be the UIC database staff and your physician. Cerner Corporation will never know your name, your UIC patient number, or any other personal information about you. On occasion, a Cerner Corporation study coordinator may ask to see your chart to verify that your medical information in the database is correct. Or, a representative from the UIC Institutional Review

Board may verify that you have given consent to participate. In these cases, your identity will remain confidential and the UIC staff will maintain control of the file that links you to your clinical information.

The only people who will know that your information is included in the database will be your physicians, nurses and the staff entering the information into the database. No information about you, or provided by you during clinic visits will be disclosed to others without your written permission. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

The database is password protected and the database can only be accessed on one designated computer. Only study staff will have access to that computer, which is also password protected.

Who should I contact if I have questions?

The researcher conducting this study is Dr. Richard Novak. You may ask any questions you have now. If you have questions later, you may contact the researchers at: 312-996-8337.

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research subject, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 (local) or 1-866-789-6215 (toll free) or email OPRS at uicirb@uic.edu.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.
You will be given a copy of this form for your information and to keep for your records.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I have been given a copy of this form.

_____ _____

Signature Date

_____

Printed Name

Signature of Researcher	Date (must be same as subject's)
Signature of Witness (if appropriate)	Date (must be same as subject's)
Printed name of Witness (if appropriate)	

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

University of Illinois at Chicago
Consent for the Telephone Behavioral Questionnaire substudy of the CDC HIV Outpatient Study Database

Why am I being asked?

You are currently a research subject in a study called the "CDC HIV Outpatient Study Database," conducted by Dr. Richard Novak from the UIC College of Medicine and Cerner Corporation in Vienna, VA. This database collects information from your medical records at this university to monitor trends in demographics (such as age, race and ethnicity), symptoms, diagnoses, treatments and disease outcomes in HIV positive patients. Several other sites in the United States participate in this study as well. Additionally, you have previously signed the addendum to this study acknowledging that on occasion voluntary surveys or questionnaires will be offered to you to complete.

We ask that you read this form and ask any questions you may have before agreeing to this telephone behavioral questionnaire substudy

Your decision to participate in this telephone questionnaire is voluntary. Your decision will not affect your participation in the main database study, nor will it affect the care you receive at FCID, nor will it affect future relations with the University. If you decide to participate, you are free to stop the questionnaire at any time without affecting that relationship.

Why is this research being done?

This telephone questionnaire is to find out more information about some of the things you have done in the last 6 months from the time of your completing this survey. Some of the questions are sensitive in nature because of the personal information requested. Due to the sensitive nature of some of the questions asked in the survey, if a loss of confidentiality were to occur, it is possible that this loss could cause potential embarrassment or discomfort to you. This information includes your sex and age, use of alcohol, use of drugs not prescribed by your

doctors, use of drugs for sexual dysfunction if you are male, and any kind of sex you may have had in the last 6 months.

How will the data be collected?

You will be given a unique questionnaire number that is different from the identification number used in the main part of the study in order to maintain confidentiality.

The questionnaire is set up so that you can skip any questions except sex and age that you do not wish to answer. It will take you anywhere from 1 to 10 minutes to complete, depending on some of your answers.

A handout with your unique 4 digit number and the instructions for completing the telephone questionnaire will be given to you once you agree to participate. You will dial the 800 phone number on the handout to get into the questionnaire. You will then punch the number that matches your response to each question.

Once you complete the questionnaire and hang up, your responses will be transmitted to the center that compiles all of the data for the main study. Your responses will be identified only by your 4 digit number that is not linked to your name. Your doctor and study staff will not know the responses you made, they will only know whether or not you completed the study.

What are the potential risks and discomforts?

There is a risk of loss of confidentiality, meaning that information collected about you could become known by others outside of the research. To keep this from happening, this questionnaire will be coded only with a unique study identification number; your name and any other identifying information such as date of birth, social security number, medical record number, address or phone number will not be associated with this number.

Are there benefits to taking part in the research?

While this questionnaire may not benefit you directly, information gathered from the questionnaire may permit a better understanding of some of the behaviors of patients in this database study. This could eventually benefit a number of persons with HIV infections, including you.

What about privacy and confidentiality?

At no time will anyone outside of UIC be able to identify you or your information through this questionnaire. All information you enter on the telephone will be under your unique study number. The only people who have access to the file that can link this questionnaire 4 digit

number to your study identification number will be the Cerner Corporation. They are the same corportation that compiles the information from the main study. Remember, as mentioned in the main study consent, Cerner Corporation will never know your name, your UIC patient number, or any other personal information about you.

Your doctor and the study staff will not know what your answers are to this questionnaire. They will only know whether or not you completed it.

Who should I contact if I have questions?

The researcher conducting this study is Dr. Richard Novak. You may ask any questions you have now. If you have questions later, you may contact the researchers at: 312-996-8337.

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research subject, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 (local) or 1-866-789-6215 (toll-free) or email OPRS at uicirb@uic.edu.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.
You will be given a copy of this form for your information and to keep for your records.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I have been given a copy of this form.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Researcher Date (must be same as subject's)

Signature of Witness (if appropriate) Date (must be same as subject's)

Printed name of Witness (if appropriate)

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

Amendment to
University of Illinois at Chicago
Consent for Inclusion in the CDC HIV Outpatient Study Database

You are currently a research subject in a study called the "CDC HIV Outpatient Study Database," conducted by Dr. Richard Novak from the UIC College of Medicine and Cerner Corporation in Vienna, VA. This database collects information from your medical records at this university to monitor trends in demographics (such as age, race and ethnicity), symptoms, diagnoses, treatments and disease outcomes in HIV positive patients. Several other sites in the United States participate in this study as well.

You are being asked to sign this addendum consent because we would like to add the use of voluntary surveys or questionnaires at the time of some of your clinic visits as a method of collecting additional data. This request of use surveys or questionnaires was not included in your original consent because at the time of your consent, we were not participating in any of the sub studies (smaller studies of the database) that are part of the ongoing database. It is hoped that the use of these surveys or questionnaires will allow us to use a more complete set of information in the sub studies. Sometimes, this data will be the same data that is in your medical records that is already collected. This addendum also includes changes to the risk and discomforts section since there is a possibility that information you provide could result in a loss of confidentiality.

Your participation in these additional surveys or questionnaires is voluntary. You can refuse to complete the survey or questionnaire and still be part of the main database study.

How will the data be collected?

From time to time, you may be asked to complete a voluntary survey or questionnaire that asks questions about your demographic information (such as age, race or ethnicity), sexual activities, drug use and medication adherence. These surveys or questionnaires will be done either by paper form or telephone at the same time as one of your scheduled clinic visits. You may refuse to participate in these surveys or questionnaires and still be part of the main study.

What are the potential risks and discomforts?

There is a risk of loss of confidentiality, meaning that information collected about you could become known by others outside of the research. To keep this from happening, the information taken from your medical records and information you provide in surveys or questionnaires will be coded with a unique study identification number.

No additional medical tests will be performed and you will not be treated any differently as a result of you information being included in the database.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I have been given a copy of this form.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Researcher Date (must be same as subject's)

_____ _____
Signature of Witness (if appropriate) Date (must be same as subject's)

_____
Printed name of Witness (if appropriate)

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

Universidad de Illinois en Chicago
Autorizaci6n Para Utilizar Y Revelar lnformaci6n De La Salud Para Investigaci6n
La Base de Datos del Estudio VIH Ambulatorio del CDC
(CDC HIV Outpatient Study Database)

Se le esta pidiendo que permita al doctor Richard Novak del Departamento de Enfermedades Infecciosas del Colegio de Medicina y a su personal que utilice y revele informaci6n protejida de la salud (protected health information, por sus siglas en ingles, PHI) que lo/la identifica para los prop6sitos de investigaci6n descritos a continuaci6n. Tambien se le esta pidiendo que permita a sus doctores y a otros proveedores de la salud que revelen PHI a estos investigadores con los prop6sitos mencionados a continuaci6n. La ley de privacidad [45 CFR Partes 160 y 164], el Acto de Responsabilidad y Aseguranza Portatil de Salud (Health Insurance Portability and Accountability ACT, por sus siglas en ingles HIPAA) provee protecci6n adicional para PHI. Debe de firmar esta autorizaci6n si quiere dejar que su PHI sea utilizado o revelado para esta investigaci6n.

Dcscripci6n de informaci611 prntcjit.la tic saint.I <Jue era utilizada y rcvclada

La informaci6n protejida de la salud que puede ser utilizada y revelada incluye toda la informaci6n colectada durante la investigaci6n descrita en el Consentimiento para Participar en la Investigaci6n titulado La Base de Datos del Estudio VIH Ambulatorio del CDC (en ingles, DC 1-1 lV Outpatient Study Database).

La informaci6n protejida de la salud que puede ser utlizada y revelada incluye toda la informaci6n protejida de la salud en sus expedientes medicos que se relacione con la investigaci6n incluyendo enfermedades y las hospitalizaciones que ocurren mientras que usted esta participando en la investigaci6n, descrito anteriormente en el Consetimiento para Participar en la Investagaci6n titulado La Base de Datos del Estudio VIH Ambulatorio del CDC (en ingles, CDC HIV Outpatient Study Database).

La informaci6n de la salud incluye informacion de todas las visitas clinicas y de cualquier hospitalizaciones dentro de su historia clinica, incluyendo informaci6n demografica como su fe ·ha d · nncimient . da L xo,raza, resultados de ·x m1en de la sangre, rayos X

radiografias), y otros examenes diagnosticos, resultados del los examenes fisicos y sinto masque lescribe en sus visitas y historias medicas y historias de medicaciones

La informaci6n protejida de la salud que pueda ser utilizada y revelada incluye la informaci6n descrita anteriormente, la cual es colectada y mantenida por sus doctores y otros proveedores de la salud identificados a continuaci6n: Los medicos y sus empleados en UIC

Uso de la investiga ci¢.n de sn informacion protegida de la salud

- Los investigadores pueden utlizar y compartir su informaci6n protejida de lasalud para llevar a cabo (conducir) lainvestigaci6n;
- Los investigadores pueden revelar su information protejida de la salud al patrocinador de la investigaci6n, Cerner Corporacion segun requerido para la investigaci6n y si mas informaci6n se necesita para confirmar la investigaci6n;
- Los investigadores pueden revelar su informaci6n protejida de la salud a otros colaboradores del estudio de investigaci6n: los Centros para el Control de Enfermedades (por sus siglas en ingles CDC).
- Los investigadores pueden revelar su informaci6n protejida de la salud a representantes de organizaciones gubernamentales (por ejemplo, Administraci6n del Alimento y de la Droga, por sus siglas en ingles FDA) donde sea requiredo por la ley; y
- Los investigadores pueden revelar su informaci6n protejida de salud al Centro Medico de la Universidad de Illinois en Chicago ya representantes de la Universidad de Illinois en Chicago incluyendo al comite de examinaci6n institucional (Institutional Review Board, por sus siglas en ingles IRB).
- Una vez que los investigadores revelen su informaci6n a cualquier persona fuera deeste estudio, puede ser revelada nuevamente y puede que no vaya a estar protegida por esta Autorizaci6n y los reglamentos federales de privacidad.

Proteccion de su informacion de la salud

Los investigadores y Cerner Corporacion estan de acuerdo en proteger su informaci6n de la salud utilizandola y revelandola como usted haya permitido en esta Autorizaci6n o como es dirigido por la ley federal y estatal. Ademas, ninguna publicaci6n sobre la investigaci6n revelara su identidad sin que usted lo autorice por escrito. Estas limitaciones continuan aun si usted decide revocar (tomar atras) esta Autorizaci6n.

Retiro de la informacion gue lo/la identifica

Una vez que la informaci6n que lo/la identifica sea retirada, la informaci6n que queda nose sujeta a esta Autorizaci6n o a HIPPA. La informaci6n restante puede ser utilizada o revelada por los investigadores bajo el permiso de la ley y puede ser utilizada y revelada para otros prop6sitos de investigaci6n.

Acceso a su inf'ormacion proteiida de la

Durante el tiempo que usted esta participando en la investigaci6n, no se le permitira ver la informaci6n colectada como parte del estudio de la investigaci6n. Una vez que termine el studio, usted tendra el derecho de tener acceso a la informaci6n otra vez.

Inclusion de su informacion protegida de la salud en una base de datos o deposito de datos.

Su informaci6n protegida de la salud se esta colectando y manteniendo indefinidamente como parte de una base de datos o un dep6sito de datos por lo tanto, esta autorizaci6n no expirara a menos que usted revoque (toma detras) su Autorizaci6n.

Sus opciones

No tiene que firmar esta Autorizaci6n, pero si no lo hace, no se le permitira participar en este estudio de investigaci6n. Sin embargo, si decide no firmar esta autorizaci6n su tratamiento, su pago o inscripci6n en algun plan de salud o su eligibilidad para recibir beneficios no se veran afectados.

Vencimiento de la Autorizacion

Esta autorizaci6n no tiene fecha de vencimiento, pero puede ser terminada si decide retirar su permiso.

Retiro o terminacion del estudio

Usted puede cambiar de opinion y revocar esta Autorizaci6n en cualquier momento. Para revocar esta Autorizaci6n, debe de escribir a: Dr. Richard Novak, M.D. UIC College of Medicine, Department oflnfectious Diseases (m/c 735) 808 S. Wood St Rm 886, Chicago, IL 60612. Sin embargo, si decide revocar esta Autorizaci6n, nose le permitira continuar participando en el studio de investigaci6n. Ademas, aunque usted revoque esta Autorizaci6n, los investigadores pueden todavia utilizar y revelar informaci6n sabre su salud que hallan obtenido ya que es necesario para mantener la veracidad de la investigaci6n y para reportar algun efecto adverso (mal evento) que le pudiera haber pasado.

Para informacion sobre mis derechos baio HIPAA

Si tiene preguntas sobre sus derechos de privacidad bajo HIPAA, comuniquese con el oficial de privacidad de la Universidad de Illinois en Chicago al (312) 996-2271.

Si todavia no ha recibido una copia de la Notificaci6n para Practicas de Privacidad (Notice of Privacy Practice), debe de solicitar una. Se le proporcionara una copia de esta Autorizaci6n para sus archivos despues de que halla sido firmada.

Firma del Sujeto:

He leido (o alguien me ha leido) la informaci6n. Se me ha dado la oportunidad de hacer preguntas y he estado satisfecho/a con las respuestas a ellas. Yo autorizo el uso y la revelaci6n de mi informaci6n protejida de salud para esta investigaci6n.

_____ _____
Firma del sujeto Fecha

_____
Nombre impreso

_____ _____
Firma del Testigo Fecha (debe ser la misma al sujeto)

_____
Nombre impreso del Testigo

Explique la necesidad de una firma de testigo y la relaci6n al sujeto

_____
_____
_____

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

Universidad de Illinois en Chicago.

Consentimiento para ser incluído(a) en la base de datos del estudio VIH ambulatorio del centro para el control de las enfermedades (CDC).

¿Por qué se me ha invitado?

Se le esta pidiendo que permita que información acerca de su tratamiento para el VIH en el Centro medico de la Universidad de Illinois (UIC) sea incluído en una base de datos nacional que ya incluye a mas de 17 centros médicos y miles de pacientes que padecen del VIH. Este estudio está siendo conducido por el doctor Richard Novak en UIC y la Corporación Cerner en Vienna, Virginia. Estamos solicitando autorización a todos los pacientes que reciben sus cuidados médicos en las consultas del Centro Médico de UIC para incluir su información en esta base de datos. Le pedimos que lea detenidamente este documento y nos haga cualquier pregunta que tenga antes de consentir a participar en esta investigación.

La decision de incluir su información en la base de datos es voluntaria. Su decisión no afectará el cuidado que usted recibe en esta clínica ni tampoco afectará sus relaciones futuras con la Universidad. Si usted decide participar, está libre a retirarse en cualquier momento sin afectar esa relación.

¿Por qué se hace esta investigación?

Esta base de datos ha sido creada para monitorear las tendencias demográficas, síntomas, diagnósticos, tratamientos y las consecuencias de la enfermedad en pacientes VIH positivos en clínicas ambulatorias alrededor de todos los Estados Unidos. Esta base de datos combinará la información de su tratamiento con la de pacientes en otros lugares de los Estados Unidos para ayudar a su médico a entender mejor las condiciones asociadas a la infección por VIH. Combinando la información de muchos pacientes diferentes podemos entender mejor los eventos inusuales y comparar los efectos de diferentes tratamientos. La base de datos puede ser usada para determinar como diferentes tratamientos son tolerados o tomados. También, los datos pueden ser usados para determinar el efecto que tiene un tratamiento en el riesgo de contraer otras infecciones ó ser hospitalizado, entre otras cosas. Diferentes investigadores, organizaciones y compañías interesadas en mejorar el tratamineto del VIH pueden usar esta información para desarrollar nuevas estrategias de tratamiento contra el VIH. Los datos pueden ser también usados para otros propósitos permitidos por la ley, incluyendo y sin limitaciones,

analísis de datos comparativos y el desarrollo, mercadeo y distribución de otros productos y servicios.

¿Como serán obtenidos estos datos?
Un número único de identificación será creado para usted después de esta visita. Después de su primera visita a la clínica una persona encargada de recopilar los datos extraerá información demográfica, incluyendo su edad, sexo , grupo étnico, y factores de riesgo para el VIH de su expediente. La información sobre sus síntomas, enfermedades diagnosticadas, medicamentos, y resultados de laboratorios también serán recolectados de su expediente luego de cada una de sus visitas. Si usted es hopitalizado, esa información también será registrada en la base de datos. Si usted ya es un paciente del centro médico de la Universidad de Illinois, la persona encargada de recoger los datos extraerá toda la información desde que usted ha sido un paciente del centro médico de UIC.

De vez en cuando, usted puede ser pedido terminar un examen o un cuestionario voluntario que haga preguntas acerca de su infomacion demografica (tal como edad, raza o pertenencia etnica), de actividades sexuales, de uso de las drogas y de adherencia a la medicacion. Estos examenes o cuestionarios seran hechos por la forma papel o el telefono en el mismo tiempo que una de sus visitas programar de la clinica. Usted puede rechazar participar en estos examenes o cuestionarios y todavia ser parte del studio principal.

¿Cúales son los riegos ó molestias como resultado de este studio?
Hay un riesgo de la pérdida de secreto, significando que la información recogida sobre usted podría saberse por otras fuera de la investigación. Para guardar esto del suceso, de la información tomada de sus expedientes médicos y de la información que usted proporciona en exámenes o los cuestionarios serán cifrados con un número de identificación único del estudio.

Ningún adicional medico las pruebas serán realizadas y le no tratarán diferentemente como resultado de usted información que es incluida en la base de datos.

¿Hay beneficios por participar en esta investigación?
Aunque la base de datos nacional no lo beneficia a usted directamente, la información recogida permitirá un mejor entendimiento de los riesgos y beneficios de diferentes tratamientos contra el VIH. Esto potencialmente podría beneficiar a un número de personas infectadas por el virus incluyéndolo a usted. Teniendo su información en una base de datos organizada puede también beneficiarlo a usted pues permite a su médico visualizar toda su información médica de manera organizada y clara en un solo lugar. En la actualidad, la base de datos utilizada por el Centro Médico de la Universidad de Illinois solo incuye información de los últimos 3 años.

Como se maneja su privacidad y confidencialidad en este estudio?
Bajo ninguna circunstancia personas fuera del personal de la Universidad podrá identificarlo a usted ó su información a través de esta base de datos. Toda la información

será incorporada a la base de datos bajo su número único. Las únicas personas que tienen acceso al expediente que pueden asociarlo a usted con su número único de identificación pertenecen al personal de UIC que trabaja con la base de datos y su médico. La Corporación Cerner nunca sabrá su nombre, número de expediente en UIC ó ninguna otra información personal sobre usted. En ciertas ocasiones, un coordinador de estudios de la Compañía Cerner puede requerir su expediente para verificar que su información médica en la base de datos es correcta. De igual manera, un representante del Consejo Examinador Institucional (IRB) puede verificar que usted ha dado consentimiento para participar. En estos casos, su identidad permanecerá confidencial y el personal de UIC mantendrá control del expediente que contiene su número único y que lo asocia a su información clínica.

Las únicas personas que sabrán que su información está incluída en la base de datos serán sus médicos, enfermeras, y el personal trabajando con la base de datos. Ninguna información sobre usted , ó proporcionada por usted durante sus visitas a nuestro centro será divulgada a terceros sin su aprobación escrita previa. Cuando los resultados de la investigación sean publicados o discutidos en conferencias, ninguna información divulgada revelará su identidad.

La base de datos está protegida por una clave secreta y solo se tendrá acceso a ella mediante un solo computador. Solo el personal del studio tendrá acceso a ese computador, el cual está protegido por una clave sereta de acceso.

¿A quién debo dirigirme si tengo preguntas?
El investigador que conduce este estudio es el Doctor Richard Novak. Puede hacer cualquier pregunta en este momento. Si tiene preguntas en el futuro, puede ponerse en contacto con los investigadores en el teléfono: (312) 996-8337.

¿Cúales son mis derechos siendo un sujeto de investigación?
Si usted siente le haber sido tratado según las descripciones en esta forma, o usted tiene cualesquiera preguntas sobre las sus derechas como tema de la investigación, usted puede llamar la oficina para la protección de los temas de la investigación (OPRS) en 312-996-1711 (local) o 1-866-789-6215 (gratis) o email OPRS en uicirb@uic.edu.

Recuerde:
Su participación en esta investigación es **voluntaria**. Su decisión de participar o no participar no afectará su relación presente o futura con la Universidad. Si decide participar, puede salir del estudio cuando lo desee sin que esto afecte su relación con nosotros.
Se le proveerá una copia de este documento para su información y sus archivos.

Firma del sujeto ó representante legal autorizado.
He leído (ó alguien me ha leído) la información arriba detallada . He tenido la oportunidad de hacer preguntas y mis preguntas han sido contestadas a mi entera satisfacción. Estoy de acuerdo en participar en esta investigación. Una copia de este documento me ha sido entregada.

_____ _____
Firma Fecha

_____
Nombre en imprenta

_____ _____
Firma del investigador Fecha (igual al del sujeto)

_____ _____
Firma del testigo (si apropiado) Fecha (igual al del sujeto)

_____ _____
Nombre en imprenta del testigo (si apropiado)

Form Approved
OMB 0920-1080 Expiration
Date: 09/29/2024

Universidad de Illinois en Chicago
Consentimiento para el cuestionario del comportamiento del teléfono substudy de la base de datos del estudio ambulatorio del centro para el control de las enfermedades (CDC)

¿Por qué me están preguntando?

Usted es actualmente un tema de la investigación en un estudio llamado "la base de datos del estudio ambulatorio del centro para el control de las enfermedades (CDC)," conducido por Dr. Richard Novak de la universidad de UIC de Medicine y Cerner Corporation en Viena, VA. Esta base de datos recoge la información de sus expedientes médicos en esta universidad para supervisar tendencias en demographics (tal como edad, raza y pertenencia étnica), síntomas, diagnosis, tratamientos y resultados de la enfermedad en pacientes del positivo del VIH. Varios otros sitios en los Estados Unidos participan en este estudio también. Además, usted ha firmado previamente la adición a este estudio que reconocía eso en encuestas sobre voluntarias la ocasión o los cuestionarios le serán ofrecidos para terminar.

Preguntamos que usted lee esta forma y hacemos cualquier pregunta que usted pueda tener antes de convenir este cuestionario del comportamiento del teléfono substudy

Su decisión a participar en este cuestionario del teléfono es voluntaria. Su decisión no afectará su participación en el estudio principal de la base de datos, ni afectará el cuidado que usted recibe en las clinicas, ni afectará las relaciones futuras con la universidad. Si usted decide participar, usted está libre parar el cuestionario en cualquier momento sin afectar esa relación.

¿Por qué se está haciendo esta investigación?

Este cuestionario del teléfono es descubrir más información sobre algunas de las cosas que usted ha hecho en los 6 meses pasados desde su terminar este examen. Algunas de las preguntas son sensibles en naturaleza debido a la información personal solicitada. Esta información incluye su sexo y edad, uso del alcohol, uso de las drogas no prescritas por sus doctores, uso de las drogas para la disfunción sexual si usted es masculino, y cualquier clase de sexo que usted pudo haber tenido en los 6 meses pasados.

¿Cómo los datos serán recogidos?

Le darán un número único del cuestionario que sea diferente del número de identificación usado en la parte principal del estudio para mantener secreto.

El cuestionario se fija encima de de modo que usted pueda saltar cualquier pregunta excepto el sexo y la edad a que usted no desea contestar. Le tomará dondequiera a partir 1 a 10 minutos a terminar, dependiendo de algunas de sus respuestas.

Un folleto con su número único de 4 dígitos y las instrucciones para terminar el cuestionario del teléfono le será dado una vez que usted acuerde participar. Usted marcará el número de teléfono 800 en el folleto para conseguir en el cuestionario. Usted entonces perforará el número que empareja su respuesta a cada pregunta.

Una vez que usted termine el cuestionario y cuelgue para arriba, sus respuestas serán transmitidas al centro que compila todos los datos para el estudio principal. Sus respuestas serán identificadas solamente por su número de 4 dígitos que no se ligue a su nombre. Su doctor y personal del estudio no sabrán las respuestas que usted hizo, sabrán solamente si o no usted terminó el estudio.

¿Cuáles son los riesgos y los malestares potenciales?

Hay un riesgo de la pérdida de secreto, significando que la información recogida sobre usted podría saberse por otras fuera de la investigación. Debido a la naturaleza sensible de algunas de las preguntas pidieron en el examen, si una pérdida de secreto era ocurrir, él son posibles que esta pérdida podría causarle la verguenza o el malestar potencial. Para guardar esto del suceso, este cuestionario será cifrado solamente con un número de identificación único del estudio; su nombre y cualquier otra información que identifica tal como fecha de nacimiento, número de Seguridad Social, número de registro médico, la dirección o el número de teléfono no será asociada a este número.

¿Hay ventajas a participar en la investigación?

Mientras que este cuestionario puede no beneficiarle directamente, la información recopilada del cuestionario puede permitir una comprensión mejor de algunos de los comportamientos de pacientes en este estudio de la base de datos. Esto podía beneficiar eventual a un número de personas con infecciones VIH, incluyendo usted.

¿Qué sobre aislamiento y secreto?

La voluntad cualquier persona fuera de UIC pueda nunca identificar le o su información a través de este cuestionario. Toda la información que usted incorpora en el teléfono estará bajo su número único del estudio. La única gente que tiene acceso al archivo que puede ligar este número del dígito del cuestionario 4 a su estudio el número de identificación será el Cerner Corporation. Son el mismo corportation que compila la información del estudio principal. Recuerde, según lo mencionado en el consentimiento principal del estudio, Cerner Corporation nunca sabrá su nombre, su número paciente de UIC, o cualquier otra información personal sobre usted.

Su doctor y el personal del estudio no sabrán cuáles son sus respuestas a este cuestionario. Sabrán solamente si o no usted lo terminó.

¿Quién debe yo entra en contacto con si tengo preguntas?

El investigador que conduce~~n~~ este estudio es Dr. Richard Novak. Usted puede hacer cualquier pregunta que usted ahora tenga. Si usted tiene preguntas más adelante, usted puede entrar en contacto con a los investigadores en: 312-996-8337.

¿Cuáles mis correcto como tema de la investigación?

Si usted siente le haber sido tratado según las descripciones en esta forma, o usted tiene cualesquiera preguntas sobre las sus derechas como tema de la investigación, usted puede llamar

la oficina para la protección de los temas de la investigación (OPRS) en 312-996-1711 (local) o 1-866-789-6215 (gratis) o email OPRS en uicirb@uic.edu.

Recuerde:
Su participación en esta investigación es voluntaria. Su decisión si o no participar no afectará sus relaciones actuales o futuras con la universidad. Si usted decide participar, usted está libre retirarse en cualquier momento sin afectar esa relación.
Le darán una copia de este forma y guardar para sus expedientes.

Firma del tema o del representante legalmente autorizado

He leído (o alguien ha leído a mí) la información antedicha. Me han dado una oportunidad de hacer preguntas y mis preguntas se han contestado a mi satisfacción. Acuerdo participar en esta investigación. Me han dado una copia de esta forma.

_____ _____
Firma Fecha

_____
Nombre impreso

_____ _____
Firma del investigador Fecha (deben estar iguales que el tema)

_____ _____
Firma del testigo (si es apropiado) Fecha (deben estar iguales que el tema)

_____
Nombre impreso del testigo (si es apropiado)

Form Approved
OMB 0920-1080 Expiration
Date: 09/29/2024

Adicion al
Universidad de Illinois en Chicago.
Consentimiento para ser incluído(a) en la base de datos del estudio VIH ambulatorio del centro para el control de las enfermedades (CDC).

Usted es actualmente un tema de la investigación en un estudio llamado "la base de datos del estudio del paciente no internado del VIH de la CDC," conducido por Dr. Richard Novak de la universidad de UIC de Medicine y Cerner Corporation en Viena, VA. Esta base de datos recoge la información de sus expedientes médicos en esta universidad para supervisar tendencias en demographics (tal como edad, raza y pertenencia étnica), síntomas, diagnosis, tratamientos y resultados de la enfermedad en pacientes del positivo del VIH. Varios otros sitios en los Estados Unidos participan en este estudio también.
Le están pidiendo firmar este consentimiento de la adición porque quisiéramos agregar el uso de exámenes voluntarios o de cuestionarios a la hora de algunas de sus visitas de la clínica como método de recoger datos adicionales. Esta petición de las encuestas sobre o de los cuestionarios el uso no fue incluida en su consentimiento original porque a la hora de su consentimiento, no participábamos en los estudios secundarios uces de los (estudios más pequeños de la base de datos) que son parte de la base de datos en curso. Se espera que el uso de éstos los exámenes o los cuestionarios permitirá que utilicemos un sistema más completo de información en los estudios secundarios. A veces, estos datos serán los mismos datos que están en sus expedientes médicos que se recoge ya. Esta adición también incluye cambios al riesgo y los malestares seccionan puesto que hay una posibilidad que la información que usted proporciona podría dar lugar a una pérdida de secreto.
Su participación en estos exámenes o cuestionarios adicionales es voluntaria. Usted puede rechazar terminar el examen o el cuestionario y todavía ser parte del estudio principal de la base de datos.

¿Cómo los datos serán recogidos?
De vez en cuando, usted puede ser pedido terminar un examen o un cuestionario voluntario que haga preguntas acerca de su información demográfica (tal como edad, raza o pertenencia étnica), de actividades sexuales , de uso de la drogas y de adherencia a la medicación. Estos exámenes o cuestionarios serán hechos por la forma papel o el

teléfono al mismo tiempo que una de sus visitas programar de la clínica. Usted puede rechazar participar en estos exámenes o cuestionarios y todavía ser parte del estudio principal.

¿Cuáles son los riesgos y los malestares potenciales?

Hay un riesgo de la pérdida de secreto, significando que la información recogida sobre usted podría saberse por otras fuera de la investigación. Para guardar esto del suceso, de la información tomada de sus expedientes médicos y de la información que usted proporciona en exámenes o los cuestionarios serán cifrados con un número de identificación único del estudio.

No se realizará ningunas pruebas médicas adicionales y le no tratarán diferentemente como resultado de usted información que es incluida en la base de datos.

Firma del tema o del representante legalmente autorizado

He leído (o alguien ha leído a mí) la información antedicha. Me han dado una oportunidad de hacer preguntas y mis preguntas se han contestado a mi satisfacción. Acuerdo participar en esta investigación. Me han dado una copia de esta forma.

_____ _____

Firma Fecha

_____

Nombre impreso

_____ _____

Firma del investigador Fecha (deben estar iguales que el tema)

_____ _____

Firma del testigo (si es apropiado) Fecha (deben estar iguales que el tema)

_____

Nombre

HOPS SITE 2004
Comprehensive Research Institute

- This site defers to the CDC IRB, and therefore does not have a yearly local IRB approval.
- English language consent

HOPS Informed Consent Forms

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

The following information is being presented to help you decide whether or not you want to participate in a research study. Please read it carefully. If there is anything you do not understand, ask the doctor.

Study Title	**"The HIV Outpatient Study (HOPS)"**
Study Site:	**St. Joseph's Comprehensive Research Institute**
Principal Investigator:	**Cynthia A. Mayer, D.O.**
Address:	**4612 N. Habana Ave. 1st Floor Research Dept., Tampa, Florida 33614**
Phone:	**(813)-840-3600**

Study Sponsor: Centers for Disease Control and Prevention (CDC) and Cerner Corporation

Study funded by: Centers for Disease Control and Prevention (CDC)

PURPOSE: You are being invited to participate in this research study because you are a patient at our clinic and you are HIV-positive. Our clinic works collaboratively with the Centers for Disease Control and Prevention (CDC) and Cerner Corporation. Cerner collects information on patients with HIV infection from medical clinics in the United States for a research study to better understand HIV disease and treatments. Data gathered by Cerner are shared with the CDC. The data may also be used for other purposes permitted by law, including comparative data analysis and the development, marketing and distribution of products and services.

We are asking you to allow us to use information gathered as a result of your treatment at this clinic. Your information will be included in the Cerner's database with data from over 9,000 HIV-positive patients seen at several clinics around the country. This database has already been existence for many years.

PROCEDURE: Data for this project will be gathered from your medical record; this will not require any effort from you. The database includes demographic information, diagnoses, laboratory results, symptoms, treatments, and hospitalizations. Information in the database is handled with the same strict privacy as your medical record.

In addition we may occasionally ask you to participate in surveys or questionnaires on various topics. These may include personal questions about sex, drug use, medication adherence, or other topics. These

surveys or questionnaires may be done on paper, by computer, or by an automated telephone system. You may refuse to participate in these special studies and still be in the main study.

This study will not require extra office visits or extra lab tests. It will cost you nothing to be in this study.

RISKS: There are no known health risks to you from participating in this study.
There is a risk of loss of privacy, meaning that information collected about you could become known to others outside of the study. To minimize the risk of this happening, your data in the database is identified only by a code number.

The additional surveys or questionnaires that you may be asked to participate in may include questions about sexual practices, illegal drug use, or similar topics. Although these surveys are private, questions about these topics may cause some discomfort or anxiety.

BENEFITS: There is no direct benefit to you from participating in this study. The information gathered in this study, however, may result in a better understanding of HIV disease and treatments, which may ultimately benefit persons with HIV infection.

Privacy: Your personal identifying information (including your name, date of birth, and possibly your medical record number) will be entered and kept in a private and secure database, separately from your medical information. Your personal identifying information cannot be seen by anyone outside of this clinic. Cerner and CDC study staff will see your medical information in the database only with your secure HOPS study participant number, not your name.

Your medical records and the consent form you sign may be inspected by authorized research investigators or the CDC to make sure the study follows federal and state regulations. From time to time, Cerner or CDC staff may review your medical records and survey data to check that your information in the database is correct. Because of this need, we cannot guarantee absolute privacy. However, CDC and Cerner staff are held to the same rules of privacy as office and study staff.

If the results of this research are published in a medical journal or presented at a conference they will not include your name or any other information that may identify you.

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit or as evidence. This protection applies to requests from federal, state or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things you need to know. The Certificate DOES NOT protect your information if federal, state or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate

also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as data collected from your medical records for this research.

PAYMENT FOR STUDY PARTICIPATION: You will not be paid to participate in this study.

VOLUNTEERING TO BE PART OF THIS RESEARCH STUDY: Your participation in this study is voluntary. You may refuse to participate or you may quit at any time. If you decide to stop taking part in this study, tell the study doctor and your data will stop being added to the study database. Any of your information already in the database at the time you quit the study may be still used for research.

If you stop participating in this study, this will not affect your medical care, benefits to which you are otherwise entitled, or ability to take part in future research studies.

TERMINATION: We do not know when this study will end. It will go on until it is stopped for some reason, or until funds are gone. The investigator or the sponsor may terminate your participation in this study without your consent**.**

QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Cynthia A. Mayer, Investigator, at (813) 840-3600.

If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the CDC's Human Research Protection at 1-800-584-8814.

CONSENT STATEMENT

By signing this form, I confirm that

- I have fully read (or someone has read and explained to me) this informed consent form describing a research study.
- I was given the opportunity ask questions and my questions have been answered to my satisfaction.

- I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form.
- I understand that I am not giving up any of my legal rights.
- I have been offered a copy of this informed consent form, which is mine to keep.

*_____	_____	_____
Signature of Participant	Printed Name of Participant	Date
_____	_____	_____
Signature of Witness (if appropriate)	Printed Name of Witness	Date

INVESTIGATOR STATEMENT:

The subject signing this consent form has had the study fully and carefully explained to him or her. I hereby certify that, to the best of my knowledge, the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study

_____	_____	_____
Signature of Investigator	Printed Name of Investigator	Date
_____	_____	_____
Signature of Person Obtaining Consent If Other than Investigator	Printed Name	Date

The research project/study and informed consent form were reviewed and approved by the CDC Human Research Protection Institutional Review Board. The board may be contacted at 1-800-584-8814.

HOPS SITE 2012 Washington Health Institute

- This site defers to the CDC IRB, and therefore does not have a yearly local IRB approval.
- English consent

Form Approved
OMB No. 0920-1080
Expiration Date: 09/29/2024

Washington Health International
Theo Wallace Hodge Jr, MD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

The following information is being presented to help you decide whether or not you want to participate in a research study. Please read it carefully. If there is anything you do not understand, ask the doctor.

Study Title: The HIV Outpatient Study (HOPS)

Study Site: Washington Health Institute

Principal Investigator: Theo Wallace Hodge Jr, MD

Address: 1140 Varnum St NE, Suite 203; Washington, DC 20017

Phone: 202-854-3840

Study Sponsor: Centers for Disease Control and Prevention & Cerner Corporation

PURPOSE: Our office works with Cerner Corporation. Cerner Corporation collects and shares information on the course of and changes in the disease, symptoms, and treatments of HIV infection. Data gathered by Cerner Corporation will be shared with the Centers for Disease Control and Prevention (CDC). Your participation in this study is voluntary and you may decide to withdraw at any time.

We are asking you to allow us to use information given by you or gathered as a result of your treatment at this clinic. This data will be used to create a database of clinical findings. The data may also be used for other purposes permitted by law, including without limitation, comparative data analysis and the development, marketing and distribution of other products and services. Your data will be grouped with data gathered on over 10,000 patients around the country. This database will span many years of treatment.

PROCEDURE: Data for Cerner Corporation is gathered from your medical record, and will not require any effort from you. The database includes demographic information, diagnoses, laboratory results, symptoms, treatments, and hospitalizations. Data in the database is handled with the same strict confidentiality as your medical record. There is no end date for this study. It will go on until it is stopped for some reason, or until funds are gone.

In addition, we may occasionally ask you to participate in surveys or questionnaires on various topics. These may include personal questions about sex, drug use, medication adherence, or other topics. These surveys or questionnaires may be done on paper, by

computer, or by an automated telephone system. You may refuse to participate in these special studies and still be in the main study.

This study will not require extra office visits or extra lab tests. It will cost you nothing to be in this study.

RISKS: There are no known health risks to you from participating in this study.

There is a risk of loss of confidentiality, meaning that information collected about you could become known to others outside of the study. To minimize the risk of this happening, your data in the database is identified only by a code number.

The additional surveys or questionnaires that you may be asked to participate in may include questions about sexual practices, illegal drug use, or similar topics. Although these surveys are confidential, questions about these topics may cause some discomfort or anxiety.

BENEFITS: There may be no direct benefit to you from your participation in this study. The information gathered in this study, however, may result in a better understanding of HIV disease and treatments, which may ultimately benefit persons with HIV infection.

FINANCIAL RESPONSIBILITY: This study will not require extra clinic visits or extra lab tests. It will cost you nothing to be in this study. You will not receive extra care if you agree to be in this study, and the cost of your health care will not change.

COMPENSATION: There will be no compensation to you for participation in this study.

ALTERNATIVES: The only other option to being in this study is to not be in this study.

CONFIDENTIALITY: Your personal identifying information (including your name, date of birth, and possibly your medical record number) will be entered and kept in a confidential and secure database, separately from your medical information. Your personal identifying information cannot be seen by anyone outside of this clinic. Cerner and CDC study staff will see your medical information in the database only with your secure HOPS study participant number, not your name.

Your medical records and the consent form you sign may be inspected by authorized research investigators or the CDC to make sure the study follows federal and state regulations. From time to time, Cerner or CDC staff may review your medical records and survey data to check that your information in the database is correct. Because of this need, we cannot guarantee absolute confidentiality. However, CDC and Cerner staff are held to the same rules of confidentiality as office and study staff.

If the results of this research are published in a medical journal or presented at a conference, they will not include your name or any other information that may identify you.

This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit or as evidence. This protection applies to requests from federal, state or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.

There are some important things you need to know. The Certificate DOES NOT protect your information if federal, state or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.

Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.

The Certificate of Confidentiality will not be used to stop sharing your information for any purpose you have consented to in this informed consent document, such as data collected from your medical records for this research.

COMPENSATION FOR INJURY: If you are harmed as a result of joining this study, there are no plans to compensate you or pay for medical costs not covered by your insurance plan. Neither the CDC, Cerner Corporation, nor Washington Health International will assume any such responsibility. The above does not prevent you from seeking such compensation.

PATIENT'S RIGHTS: As a research study patient, you have the right to ask questions. You should not agree to be in this study until all your questions have been answered. You have the right to withdraw from this study at any time. If you chose to withdraw from this study, your care will not change. If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the CDC's Human Research Protection at 1-800-584-8814.

If you have any questions or problems related to this research study, or if you wish to withdraw from this study, you may call Dr. Theo Wallace Hodge Jr at 202-854-3840.

CONSENT:

I, _____, hereby authorize Dr._____ and Cerner Corporation to use any information given by me, or by my doctors as a result of my treatment. I know that this information will be used by members of Cerner Corporation and the Centers for Disease Control and Prevention for studies on the causes of illness, treatments, and outcomes of patients with HIV.

I have been given the chance to ask questions, and am satisfied with the answers I have received. I know that I will be given a copy of this consent form. I know that I may withdraw from this study at any time, and that withdrawing will not affect my treatment. I have been given the name and number of a contact person for questions, concerns, or to call if I wish to withdraw.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a patient or a participant in a research study.

_____		
Patient Name	Patient Signature	Date
_____		
Name of Witness (if appropriate)	Witness Signature	Date

INVESTIGATOR STATEMENT:
The subject signing this consent form has had the study fully and carefully explained to him or her. I hereby certify that, to the best of my knowledge, the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study.

_____		
Signature of Investigator	Printed Name	Date
_____		
Signature of Person Obtaining Consent if Other than Investigator	Printed Name	Date