Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

HIV Outpatient Study (HOPS)
Attachment 4

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

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:	**Infectious Disease Research Institute**
Principal Investigator:	**Cynthia Mayer**
Address:	**4600 N. Habana Ave** **Suite 23** **Tampa, FL 33614**
Phone:	**813-870-4760**

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.

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.

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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 Mayer**, Investigator, at **813-870-4760**.

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

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_____	_____	_____
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.

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

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: **Douglas J. Ward**

Address: **1737 20th Street NW**
Washington, DC 20009

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 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.

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.

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**.**

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QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Douglas J. Ward, 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

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_____	_____	_____
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.

Form Approved
OMB No. 0920-1080
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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: **Denver Infectious Disease Clinic**

Principal Investigator: **Ken Greenberg**

Address: **4545 E. 9th Ave**
Ste 120
Denver, Co 80220

Phone: **303-393-8050**

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 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.

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.

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**.**

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QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Ken Greenberg, Investigator, at **303-393-8050**.

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

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_____	_____	_____
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.

Form Approved
OMB No. 0920-1080
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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:	**Northwestern University**
Principal Investigator:	**Frank Palella**
Address:	**645 N. Michigan Ave** **Suite 900** **Chicago, IL 60611**
Phone:	**312-695-5053**

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.

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BENEFITS: There is no direct benefit to you from 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.

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.

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**.**

Form Approved
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QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Frank Palella, Investigator, at **312-695-5053**.

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

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_____	_____	_____
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.

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

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: **SUNY Stonybrook Medical Center**

Principal Investigator: **Jack Fuhrer**

Address: **205 North Belle Meade Rd**
East Setauket, NY 11733

Phone: **631-444-2113**

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.

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BENEFITS: There is no direct benefit to you from 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.

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.

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**.**

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Jack Fuhrer, Investigator, at **631-444-2113**.

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

Form Approved
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_____	_____	_____
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.

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

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: **Temple University**

Principal Investigator: **Ellen Tedaldi**

Address: **1316 W. Ontario Street**
Jones Hall Suite 808
Philadelphia, PA 19140

Phone: **215-707-4511**

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 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.

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.

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**.**

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Ellen Tedaldi, Investigator, at **215-707-4511**.

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

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

_____	_____	_____
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.

Form Approved
OMB No. 0920-1080
Expiration Date: xx/xx/xxxx

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: **Apex Research LLC**

Principal Investigator: **Mia Scott**

Address: **300 S. Jackson Street**
Suite 100
Denver, Co 80209

Phone: **303-321-0222**

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.

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BENEFITS: There is no direct benefit to you from 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.

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.

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**.**

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Expiration Date: xx/xx/xxxx

QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Mia Scott, Investigator, at **303-321-0222**.

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

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- I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form.
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_____	_____	_____
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INVESTIGATOR STATEMENT:

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Signature of Investigator	Printed Name of Investigator	Date
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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: **University of Illinois-Chicago**

Principal Investigator: **Rick Novak**

Address: **808 S. Wood Street**
Chicago, IL 60612

Phone: **312-996-6763**

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.

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

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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.

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

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OMB No. 0920-1080
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QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Rick Novak, Investigator, at **312-996-6763**.

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

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

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