

HIV Outpatient Study (HOPS)
Attachment 4 Informed Consent Forms

Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-1080)

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: Bienvenido Yangco

Address: 4620 N. Habana Ave
Suite 203
Tampa, FL 33614

Phone: 813-875-4374

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.

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. **Bienvenido Yangco**, Investigator, at **813-875-4374**.

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 Printed Name of Witness Date
(if appropriate)

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 Printed Name Date
If Other than Investigator

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.

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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.

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

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Signature of Investigator Printed Name of Investigator Date

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

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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Study Title "The HIV Outpatient Study (HOPS)"

Study Site: Denver Infectious Disease Clinic

Principal Investigator: John Hammer

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.

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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.

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. John Hammer, 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 Printed Name of Witness Date
(if appropriate)

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 Printed Name Date
If Other than Investigator

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.

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.

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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.

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.

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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.

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. 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

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- 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.

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Signature of Participant Printed Name of Participant Date

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

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 Printed Name Date
If Other than Investigator

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.

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.

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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.

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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.

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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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.

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Signature of Investigator Printed Name of Investigator Date

Signature of Person Obtaining Consent Printed Name Date
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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.

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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 Printed Name of Witness Date
(if appropriate)

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 Printed Name Date
If Other than Investigator

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.

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: Ben Young

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.

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.

QUESTIONS AND CONTACTS:

If you have any questions or problems related to this research you may call Dr. Ben Young, 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.

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Signature of Investigator Printed Name of Investigator Date

Signature of Person Obtaining Consent Printed Name Date
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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: **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.

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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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.

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.

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Signature of Investigator Printed Name of Investigator Date

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

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