



St. Vincent

**ST VINCENT HOSPITAL INSTITUTIONAL REVIEW BOARD
INDIANAPOLIS, INDIANA
MEDICAL RESEARCH INFORMED CONSENT FORM**

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

SUB-INVESTIGATORS:

R2009-

SPONSOR:

PROTOCOL VERSION DATE:

PATIENT NAME _____ **DOB** _____

You are invited to take part in a research study [*insert a general statement about the study*]. You were selected as a possible participant because [*explain how the subject was identified*]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

If you have any questions regarding this study, you may contact [*insert investigator's name*] or one of the sub-investigators listed above at [*insert investigator's contact information*]. If you have any questions regarding your rights as a research patient you may contact the St. Vincent Hospital Institutional Review Board at (317) 338-2194.

PURPOSE:

The purpose of this study is to [*explain the research question and purpose in language understandable to the subject, e.g., eighth grade level*]. (If the study involves the use of an

investigational drug or device, state this and clarify that “investigational” means it is not approved by the Food and Drug Administration (FDA)).

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of *[insert number]* subjects who will be participating in this research *[indicate locally and nationally, if multi-center study]*.

PROCEDURES:

If you agree to be in the study, you will do the following things:

(In language understandable to the subject, give in detail, preferably in chronological order, all procedure, including surveys, focus groups, audio or video taping, assignment to study groups, medications, etc., which will be used in the study, including where they will be performed, their frequency, and the total duration of the study. Identify which procedures are experimental and which are standard procedures. If blood is to be drawn, explain how and from where the blood will be drawn, e.g., “from a vein in your arm.” Indicate the total number of times blood will be drawn, the amount of blood to be drawn each time, and the total amount of blood to be drawn over the course of the study. Translate the amount to be drawn to common measurement terms, such as teaspoonfuls or cupfuls).

RISKS/DISCOMFORTS:

(Define the risks, side effect, discomforts of each of the procedures to be employed in the study (i.e. physical, psychological, social, legal in lay language). Give the side effects of all medications to be given to the subjects for the purpose of the study.)

While on the study, the risks are *[explain each, including their likelihood]*:

(e.g.: The risks of completing the survey are being uncomfortable answering the questions.)

(e.g.: The risks of possible loss of confidentiality)

(e.g.: The risks of drawing blood include, pain, bruising, and rarely, infection.)

(e.g.: The side effects associated with taking Cimetidine are mild diarrhea, mild elevations in liver enzymes, confusion, sleepiness, agitation, depression, anxiety, hallucinations and headaches. Enlargement of the breasts and reversible impotence can occur when males take the drug at high doses (1200-2400 mg daily). In rare instances, hair loss, rash, decrease in number of red and white blood cells and blood platelets as well as severe inflammation of the kidneys and allergic reactions can occur.)

(As appropriate :) There also may be other side effects that we cannot predict. **OR** This study may involve currently unforeseeable risks to you and to an embryo or fetus if you should become pregnant.

(Give measures that will be employed to minimize the risks and side effects listed above.)

(e.g.: Blood will be drawn by experienced technicians and whenever possible it will be obtained at a time when blood is being obtained for other tests your doctor has ordered.)

(e.g.: While you are receiving Cimetidine, you will be questioned weekly about possible side effects; your blood and kidney function will be monitored by the blood tests we are obtaining.)

(If there are significant psychological risks to participation, the subject should be told under what conditions the research will terminate the study).

(e.g.: While completing the survey, you can tell the researcher that you feel uncomfortable or do not care to answer a particular question.)

(e.g.: Explain any psychological, social, or medical services that may be required because of research participation such as counseling, social support services or medical services.)

BENEFITS:

While there is no guarantee that you will benefit, the knowledge gained from your participation may help others. The benefits to participation that are reasonable to expect are ***[describe any direct benefit to the subject or benefit to others, which may reasonably be expected from the research.]***

(If there is no direct benefit to the subject, state it.) While there is no guarantee that you will benefit, the knowledge gained from your participation may help others.

Note: payment to subjects is not considered a benefit of participating in the study].

ALTERNATIVE TREATMENT:

Instead of being in the study, you have these options: ***[As appropriate, give alternative procedures or courses of treatment, if any, that might be advantageous to the subjects. If the only alternative is not participating, state this].***

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published ***[and databases in which results may be stored]***.

(If tape recordings or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be destroyed)

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the St. Vincent Hospital Institutional Review Board or its designees, ***(use the following as appropriate)*** study sponsor, and (as allowed by law) state or federal agencies (specifically the Office for

Human Research Protections (OHRP) and the Food and Drug Administration (FDA), (*federal agencies*) the National Cancer Institute (NCI) (*for research funded or supported by NCI*), the National Institutes of Health (NIH) (*for research funded or supported by NIH, etc.*) may need to access your medical and/or research records.

COSTS:

(If there are no costs associated with participation in the study, state this).

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: *[list the procedures, tests, office visits, medications, etc. for which the subject or the subject's insurance is responsible. If appropriate, state that all standard of care procedures, drugs, tests, etc. will be the responsibility of the subject or his/her insurance.].* You will not be responsible for these study-specific costs: *[list the procedures, tests, visits, medications, etc. for which the study will pay].*

(As appropriate, "If during the study, [name of study drug/device] becomes commercially available, you may have to pay for the amount of drug needed to complete the study.")

PAYMENT

You *[will/will not]* receive payment for taking part in this study **[include details and any conditions of payment]**.

COMPENSATION FOR INJURY

(If a source of funds for payment of treatment costs is NOT available, include the following statement:)

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

(If a source of funds for payment of treatment costs IS available, the source and conditions for payment of those costs should be identified.)

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher (*Name of Investigator*) at (*telephone number*). If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the St. Vincent Hospital Institutional Review Board at (317) 338-2194. After business hours, please call *[state alternate number, e.g. on-call physician, pager number]*.

In the event of an emergency, you may contact *[name of investigator]* at *[24-hour emergency number]*.

(As appropriate for investigational drug studies:) If you are unable to reach the investigator at the above number, in an emergency you may contact *[insert contact information]*.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the St. Vincent Hospital Institutional Review Board at (317) 338-2194.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with *[e.g. St. Vincent Hospital, Primary Care Center]*. *(If withdrawal from the study prior to completion could pose risk to the subject, state what those risks might be and how orderly termination will occur)* Note that our St Vincent IRB does not allow a requirement that the subject has to withdraw “in writing” we prefer “by contacting the investigator” or similar].

(As appropriate) Your participation may be terminated by the investigator without regard to your consent in the following circumstances: *[state when and why this might happen and how orderly termination will occur]*.

(As appropriate) You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by *(Sponsor/Investigator)* if *(give reason for premature termination)*.

LEGAL RIGHTS:

You are not waiving any legal rights or releasing the hospital, your physician or the sponsor of this study from liability for negligence by signing this consent form.

(As appropriate - Use the following two sections and appropriate paragraph)

USE OF SPECIMENS

As this is a research institution, specimens obtained in medical situations may later be used for research purposes. The investigator intends to include specimens taken from you along with other specimens that may also be used in an attempt to develop products to be sold, and it is not the intention of the investigator to enter into an agreement with you to become partners in sharing the profits or losses in the sale of those products.

PREGNANCY STATEMENT:

Women of childbearing potential should not be pregnant while on this study and should use an acceptable method of pregnancy prevention. If you suspect that you are pregnant you will inform your physician immediately **[this is the only acceptable language by The St Vincent IRB for pregnancy prevention]**.

VOLUNTARY CONSENT

(This section should be in first person) I certify that I have read this informed consent, or it has been read to me, and that I understand its contents, and voluntarily agree to participate in this research study.

Please keep a copy of this Informed Consent for your records.

_____ Patient (printed name) <i>Required of all patients seven (7) years of age and older.</i>	_____ Date
_____ Patient Signature <i>Required of all patients seven (7) years of age and older.</i>	_____
_____ Legal Representative (printed name) & Relationship to Patient (if applicable)	_____ Date
_____ Legal Representative Signature (if applicable)	_____
_____ Principal Investigator (printed name)	_____ Date
_____	_____

Principal Investigator Signature

Witness to Patient Signature (printed name)
(must be someone other than physician, patient, or legal representative)

Date

Witness Signature

Printed Name of Person Obtaining Signature

Signature of Person Obtaining Signature

Date

ST. VINCENT

RESEARCH PATIENT BILL OF RIGHTS

I have been asked to participate in a research study. Before I make a decision on whether or not I want to participate in this study, I have the right:

1. To be told the reason why this study is being done.
2. To be told how the study will be done and what kind of medication or device will be used
3. To know the different types of side effects to expect from my participation in the study.
4. To know what benefits I will receive from my participation in this study.
5. To be told what other treatment is available for me, including the risks and benefits.
6. To be told what other treatments are available to me after the study has been completed.
7. To be given an opportunity to ask any questions concerning the medical experiment or the procedures involved.
8. To stop the study at any time and know I will continue to receive good care.
9. To receive a copy of the patient rights and the signed and dated informed consent form.
10. To make up my mind about being part of the study without feeling forced to participate.