

INDIANA UNIVERSITY SOUTHEAST
INFORMED CONSENT STATEMENT

" [Redacted]

You are invited to participate in a research study of [Redacted]. You were selected as a possible subject because [Redacted]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by [Redacted]. It is funded by [Redacted].

STUDY PURPOSE

The purpose of this study is to [Redacted]

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of [Redacted] subjects who will be participating in this research.

PROCEDURES FOR THE STUDY:

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

RISKS OF TAKING PART IN THE STUDY:

While in the study, the risks [Redacted] are:
[Redacted]

[Explain measures that will be employed to minimize the risks and side effects listed above.]

Examples include:

[REDACTED]

BENEFITS OF TAKING PART IN THE STUDY:

The benefits to participation that are reasonable to expect are [REDACTED]

ALTERNATIVES TO TAKING PART IN THE STUDY:

Instead of being in the study, you have these options: [REDACTED]

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 [REDACTED]

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 IUB Institutional Review Board or its designees, the 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), if applicable, the National Institutes of Health (NIH) [for research funded or supported by NIH], etc., who may need to access your medical and/or research records.

COSTS

Taking part in this study may lead to added costs to you. You will be responsible for these study-specific costs: [REDACTED]

PAYMENT

You (will/will not) receive payment for taking part in this study. [REDACTED]

COMPENSATION FOR INJURY [For research studies that are greater than minimal risk]

[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.] [REDACTED]

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher " " at " "

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 IU Southeast Research Office, Academic Affairs Office, University Center South, Room 152, New Albany, IN 47150-6405, 812-941-2210 or by email at tandrews@ius.edu.

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 the investigator(s).

USE OF SPECIMENS

If specimens obtained as part of the study will be used for commercial use, include the following statement: 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.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name: _____

Subject's Signature: _____ **Date:** _____
(must be dated by the subject)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ **Date:** _____

**NOTE: Printed name lines are optional.