**Study Title:**

***List the title in this section exactly as it appears on the IRB Application.***

**Authorized Study Personnel**

***List by name those personnel authorized to document consent as listed in the IRB Application. Use the following personnel labeling: Principal Investigator and Secondary Investigator(s). Include day phone numbers for all listed individuals. For greater than minimal risk studies, consider including night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.***

**Principal Investigator:** John Smith, MA Office: (816) 472-1000

**Secondary Investigator**: Jane Doe, Ph.D. Office (816) 472-2000

CONCISE SUMMARY

In general, we would expect that to satisfy § \_\_.116(a)(5)(i), the beginning of an informed consent would include a concise explanation of the following:

(1) the fact that consent is being sought for research and that participation is voluntary;

(2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;

(3) the reasonably foreseeable risks or discomforts to the prospective subject;

(4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and

(5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

As a general matter, a brief description of these five factors would encompass the **key information** most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research, as required by § \_\_.116(a)(5)(i) and § \_\_.116(a)(4).

**KEY INFORMATION**

You are being asked to take part in this research study because you ***[insert condition here]***. Research studies are voluntary and include only people who choose to take part. The purpose of this research is ***[insert purpose here]***. The total amount of time you would be in this study is ***[insert duration of subject participation here]***. During your participation you will be involved in ***[insert procedures participate will be asked to participate in].*** Taking part in this research involves the following risks or discomforts: ***[insert reasonably foreseeable risks or discomforts here]***. Taking part in this study includes the following benefits: ***[insert reasonably expected benefits here]*** OR ***There are no benefits to you for taking part in this study.*** You have the alternative of not taking part in this study OR The alternative to taking part in this study is ***[insert alternative procedures or courses of treatment that might be advantageous to the subject].***

Please read this consent form carefully and take your time making your decision. As the researcher(s) discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. Please talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the researcher(s) if you are taking part in another research study.

***(Insert one of the following if applicable)***

1. ***(PI Name)*** will conduct the study and it is funded by **(*Sponsor Name*)**. The sponsor of this study, ***(Sponsor Name)***, will pay University of Missouri, Kansas City (UMKC) to perform this research, and these funds may pay part of ***(PI Name’s)*** salary.
2. ***(PI Name)*** will conduct the study and it is funded by **(*Sponsor Name*)**. The sponsor of this study, ***(Sponsor Name)***, will pay University Health (formerly Truman Medical Centers) to perform this research, and these funds may pay part of ***(PI Name’s)*** salary.

***OR if relevant:***

1. A grant from [e.g., the National Institutes of Health (NIH), research foundation like the American Lung Association, etc.,] will sponsor this study. Portions of ***(PI’s Name)*** and his/her research team’s salaries will be paid by this grant.

# WHY IS THIS STUDY BEING DONE?

The purpose of this study is to…….

**Please note**:***If you are using an investigational drug, drug combination, biologic and/or device, please always indicate what is FDA approved and what is investigational, and define “investigational.”***

***For example, “The word “investigational” means the study drug or device or biologic is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).” Refrain from using “medicine,” “treatment,” or “therapy” for the investigational drug or device. Instead, use study drug, study procedures, study processes, etc.***

***If you will be using an investigational procedure, such as an investigational surgical procedure or innovative diagnostic procedure, please clearly identify it as investigational.***

# HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately \_\_\_ people will take part in this study at \_\_\_ **(*if multicenter, add number of hospitals/medical******facilities)*** different hospitals and medical facilities, and approximately \_\_\_\_ people will take part at **[UMKC or University Health]**.

# WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

* Physical exam and medical history
* Vital signs
* Blood tests
* Electrocardiogram (EKG), a tracing of the electrical activity of the heart

Also describe in this section the procedures, study drug, samples, questionnaires, follow-up, etc., (whatever is applicable to your study).

**For randomized studies:** You will be randomly assigned (like the flip of a coin) to receive either ***(arm 1 or arm 2)***. You have a ( ) in ( ) chance of receiving study drug. ***For studies with more than 2 arms, use “like drawing numbers from a hat.”***

***When describing what is involved in the study, consider laying out a timeline. For example, on Day 1, you will have an EKG and two tablespoons of blood will be drawn from your arm by needle stick for blood tests. On Day 2, you will receive the study drug intravenously (into your vein) for two hours (and so forth). You can also create a timeline using visits. For example, on Visit 1, you will receive study drug to take daily until Visit 2.***

**Please note: *If your study will use a placebo, please define placebo. For example, “A placebo is an inactive substance given in the same form as the active drug, Paclitaxel.”***

***Be sure to disclose:***

* *The identification of any procedures that are investigational/experimental. (May be omitted if there are none.)*
* *A statement that notes the possibility that the Food and Drug Administration may inspect the records. (May be omitted for research that is not FDA-regulated.)*
* *A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.*
* *Procedures for orderly termination of participation by the subject.*
* *A statement that “If you do not sign this consent form, you will continue to receive care, but not as a part of this study.”*
* *A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)*

# HOW LONG WILL I BE IN THIS STUDY?

***Describe here how long the study will be (in weeks, days or months). Describe also (if applicable) if you intend to collect follow-up information and how long this will be done. For example, until six months after last study drug dose, for the rest of your life, etc.***

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

Clinically relevant results of this research will be communicated with you (describe when and under what conditions, if applicable).

# WHAT ARE THE RISKS OF THE STUDY?

**Please note: *The risk section should only contain the risks associated with study procedures. Risks of standard care procedures should not be included in the consent form.***

**Please note: *For minimal risk studies (such as questionnaires/surveys) where loss of confidentiality or psychological stress is the only risk; these need to be listed.***

***For example: There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.***

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study researcher and your regular health care provider if you choose.

***(Study Drug Name)*** may cause some, all or none of the side-effects listed below.

More likely ***(insert more common side effect below using bullets)***



Less Likely ***(insert less common side effect below using bullets)***



For Those of Reproductive Potential ***(insert this risk section if applicable to your study)***

**Female (modify as appropriate)**

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you can continue in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study and for **(specify if applicable)** months afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

**Male (modify as appropriate)**

Your participation in this research may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for **(specify if applicable)** months afterward. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study researcher, and she should promptly notify her doctor.

**Risks of Drawing Blood:** ***(insert this risk statement if applicable to your study)***

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

**Drug and Food Interactions:** ***(insert this risk statement if applicable to your study)***   
For your safety, you must tell the study researcher or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

**Risks of Discontinuation of Treatment:** ***(insert this risk statement if applicable to your study)***

During the discontinuation of medication(s) period, your symptoms of \_\_\_\_\_\_ may get worse. Please discuss the risks of discontinuing prescribed treatments or therapies with the study researcher.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

# ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. ***(Insert the potential direct medical benefit here. If there is none, alter the initial sentence to indicate that.)*** We hope that in the future the information learned from this study will benefit other people with your condition. ***(Note that this is merely sample language; please modify it to fit your protocol.)***

# WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Instead of being in this study, you have the following alternatives:

Please talk to your doctor about these and perhaps other options.

**Please note: *If the only alternative is not to participate, please leave this section out of the consent form.***

# WILL MY INFORMATION BE KEPT CONFIDENTIAL?

*The University of Missouri System,* [*Authorization No. 00-018*](https://www.umsystem.edu/ums/fa/management/records/guide/rrg01801) *requires research data to be retained for 7 years after the final report.*

To comply with hospital accreditation requirements, the bar code label on this consent form is used to link the consent form to your permanent medical record at UNIVERSITY HEALTH. If you do not want this consent form or your participation in this study to be a part of your permanent medical record you cannot participate in this study.

***Please edit the following language as appropriate***

Participation in research involves some loss of confidentiality. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be disclosed outside of the University or hospital if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to **[Sponsor Name]** and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include **[representatives from the Food and Drug Administration]**, representatives and affiliates of **[Sponsor Name]**, the UMKC Institutional Review Board, [**add others as appropriate**], and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

***For ALL NIH funded research and any other research with a Certificate of Confidentiality:***

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy.  With this Certificate, the researchers may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. you have consented to the disclosure, including for your medical treatment; or
3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).  
   
You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Finally, you should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

***Expiration date or event for the retention of records***

The study results will be retained in your research record for at least seven (7) years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results. Any research information in your medical record will be kept indefinitely.

***OR***

The study results will be retained in your research record forever. Any research information in your medical record will also be kept indefinitely.

***For blinded studies, please include the following statement regarding temporary restriction of access to study records:***

Some information collected in research studies is maintained in your medical record. However, for this study that information will be inaccessible until the end of the study, unless your physician decides that it is necessary for your care.

***For all funded studies:***

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

***For all studies:***

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of UNIVERSITY HEALTH, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

***If applicable:***

A representative from the sponsor may be present at certain study visits/procedures.

# WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. If a procedure or service is not covered by your insurance or Medicaid/Medicare, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with **[the PI].**

***Insert if applicable:***

The study sponsor ***[Sponsor Name]*** has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures (including the device, if applicable) that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

***(If sponsor is providing drug/biologic)***

***[Sponsor]*** will provide the study drug/biologic free of charge to you. At the end of the study, or if you decide to withdraw from the study before it ends, you may be asked to return all unused study drug. Your study researcher may request that you return for a checkup before you stop your study drug/biologic if he/she thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

**Please note: *If there are potential additional costs to the subject for participating in the study (and they are not being compensated for them), you must clearly state this in this section.***

Taking part in this study may cost you and/or your insurance company more than the cost of getting regular medical treatment. (Include cost details here).

**Please note: *If there are potential additional costs to the subject for participating in the study (and they are not being compensated for them), you must clearly state this in this section.***

# WHAT ABOUT COMPENSATION?

You will be compensated up to $( ) for your expenses related to your participation (parking, gas, and time) in this study. To comply with federal income tax requirements, payments to you are reportable income. Your name, address, and social security number may be provided to the accounting department and others at University Health so that your compensation may be processed.

***(Please do not use decimal point. For example, use $25, not $25.00)***

**Please note: *Compensation must be prorated so that if a subject withdraws from the study, the subject will receive compensation for the parts of the study he/she completed.***

# WHAT ABOUT RESEARCH RELATED INJURIES?

Participation in this research study does not take the place of routine physical examinations or clinic visits to your personal physician.

***[UNIVERSITY HEALTH Template for sponsored research projects - If applicable, this statement must be included]***

UNIVERSITY HEALTH will provide medical attention to you if you suffer any injury or harm caused by the study drug or study required procedure. The study sponsor and UNIVERSITY HEALTH will decide if the injury or harm was a result of participation in the study. The study sponsor shall be responsible for the expenses caused by any study-related injury. UNIVERSITY HEALTH will not bill third party payers for any expenses related to treatment from injuries caused by this research study. UNIVERSITY HEALTH or the sponsor will provide no other compensation of any type.

***[UNIVERSITY HEALTH Template for non-sponsored projects - If applicable, this statement must be included]***

UNIVERSITY HEALTH will provide medical attention to you in the event of any medical emergency while present at UNIVERSITY HEALTH from participation in this research, whatever the cause at the usual charge and you will have the benefit of the coverage of any existing health insurance you own.

***[This statement must be included]*** UMKC appreciates people who help it gain knowledge by being in research studies. It is not UMKC policy to compensate human subjects in the event this research results in injury. The University, in fulfilling its public responsibility, has provided medical, professional and general liability insurance or self-funded coverage for any injury in the event such injury is caused by the negligence of the University, its faculty and staff. In the event you have suffered an injury as the result of participation in this research study, you are to advise the researcher listed on page one and contact the University Risk Management Office, telephone (573) 882-1181 who can review the matter and provide further information.

# WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

***One of the following 6 sections must be included in every consent form. Please determine which category applies to your study, and add the appropriate section.***

1. ***For Studies involving an FDA regulated product (drug, device, or biologic) (Outside Sponsor)***

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad side effect) related to the study. If an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. If you withdraw from the research ***[Describe any consequence of withdrawal. For example, subjects on a diabetes drug may experience loss of control of their diabetes unless they are switched to another medication. Subjects on corticosteroids may experience life-threatening problems unless the subject is slowly taken off the steroids. Omit if there are no adverse consequences.]*** If you do decide to withdraw, we ask that you contact ***[insert PI’s name here]*** andlet ***[him/her]*** know that you are withdrawing from the study. ***[His/her]*** contact information is ***[enter contact information here]***. You will be asked to ***[describe any procedures for orderly termination from the protocol. For example, switching to another diabetes drug, tapering of steroids, or referral to another health care provider.]***

1. ***For Studies involving an FDA regulated product (drug, device, or biologic) (Internally Sponsored)***

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad side effect) related to the study. If an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. If you withdraw from the research ***[Describe any consequence of withdrawal. For example, subjects on a diabetes drug may experience loss of control of their diabetes unless they are switched to another medication. Subjects on corticosteroids may experience life-threatening problems unless the subject is slowly taken off the steroids. Omit if there are no adverse consequences.]*** If you do decide to withdraw, we ask that you contact ***[insert PI’s name here]*** andlet ***[him/her]*** know that you are withdrawing from the study. ***[His/her]*** contact information is ***[enter contact information here]***. You will be asked to ***[describe any procedures for orderly termination from the protocol. For example, switching to another diabetes drug, tapering of steroids, or referral to another health care provider.]***

1. ***For Studies not involving FDA regulated products (Outside sponsor)***

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad side effect) related to the study. If an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. If you withdraw from the research ***[Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.]*** If you do decide to withdraw, we ask that you contact ***[insert PI’s name here]*** andlet ***[him/her]*** know that you are withdrawing from the study. ***[His/her]*** contact information is ***[enter contact information here]***. You will be asked to ***[describe any procedures for orderly termination from the protocol. For example, return electronic diary, or referral to another health care provider.]***

1. ***For Studies not involving FDA regulated products (Internally sponsored)***

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad side effect) related to the study. If an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. If you withdraw from the research ***[Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.]*** If you do decide to withdraw, we ask that you contact ***[insert PI’s name here]*** andlet ***[him/her]*** know that you are withdrawing from the study. ***[His/her]*** contact information is ***[enter contact information here]***. You will be asked to ***[describe any procedures for orderly termination from the protocol. For example, return electronic diary, or referral to another health care provider.]***

1. ***For Minimal Risk Studies (Risk no greater than the typical daily experience of a healthy person) (Outside sponsor)***

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. ***[Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.]*** If you do decide to withdraw, we ask that you contact ***[insert PI’s name here]*** andlet ***[him/her]*** know that you are withdrawing from the study. ***[His/her]*** contact information is ***[enter contact information here]***. You will be asked to ***[describe any procedures for orderly termination from the protocol. For example, return electronic diary, or return equipment or videotapes.]***

1. ***For Minimal Risk Studies (Risk no greater than the typical daily experience of a healthy person) (Internally sponsored)***

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. ***[Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.]*** If you do decide to withdraw, we ask that you contact ***[insert PI’s name here]*** andlet ***[him/her]*** know that you are withdrawing from the study. ***[His/her]*** contact information is ***[enter contact information here]***. You will be asked to ***[describe any procedures for orderly termination from the protocol. For example, return electronic diary, or return equipment or videotapes.]***

***Additional information that must be shared with the subject if applicable:***

In addition, you must return all unused study drug to ***[insert PI’s name here]*** or ***[his/her]*** staff.

***and/or***

***[Insert PI’s name here]*** may ask you to return for a checkup before you stop your study drug if ***[he/she]*** thinks that stopping the drug suddenly may harm you.

***and/or***

***[He/she]*** may also ask you to complete the tests that would ordinarily occur when a person completes the study.

***For all studies***

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your researcher may decide to take you off this study if your condition gets worse, if you have serious side effects, or if ***[insert PI’s name here]*** determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include … ***[describe anticipated circumstances under which participation may be terminated by the researcher without regard to the participant’s consent.]*** If this occurs, you will be notified and other options will be discussed with you.

***For withdrawal of samples***

If you agree to allow your ***[tissue/blood/cells]*** to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact ***[insert PI’s name here]*** and let ***[him/her]*** know you are withdrawing your permission for your identifiable ***[tissue/blood/cells]*** to be used for future research. ***[His/her]*** contact information is ***[enter contact information here]***. At that time we will ask you to indicate in writing if you want the unused identifiable ***[tissue/blood/cells]*** destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

***Required if any identifiable samples or data are collected and used for future research purposes***

Your ***[samples and/or data]*** may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. ***(may be removed if no specimens are collected)***

***Required language for all studies registered on the web site ClinicalTrials.gov***

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

# WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact ***(insert PI’s Name)*** at ***(PI’s Number with Area Code)*** during regular business hours and at ***(PI’s 24-hour Number with Area Code)*** after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information about research participant’s rights, contact the UMKC Institutional Review Board (IRB) Office at (816) 235-5927.

# STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information. I have read or had read to me this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Subject

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Signature of Subject Date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date Time

***If applicable, add or substitute any of the following:***

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Printed Name of Legal Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legal Representative Date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to Subject