**RESEARCH CONSENT FORM**

**Study Title**

**PI Name**

**PI Contact Information**

You are being invited to join a research study being done at the University of Kansas Medical Center (KUMC) by [PI Name.] Being in this study is optional. You can decide not to participate or stop at any time. Regardless of your decision, you will still get the same care from your health care team.

**Why is this study being done?**

Insert 2 – 3 sentences about why the study is needed and what researchers hope to learn.

**What am I being asked to do?**

Describe the study procedures in simple, lay terms. Below is a basic outline that might be applicable for minimal risk interventions. Feel free to make adjustments if your study does not fit this pattern.

This study involves XX visits to our [clinic/research center]. Your participation in the study will have three parts:

Part 1

We will begin the study by [asking you questions about, taking measurements of…] your current [health, lifestyle, medical history, beliefs, skills, etc.]. It will take about [time involved.]

Part 2

Describe the intervention the subject will experience. Discuss the study groups and randomization or comparisons, intervention process, and time involved.

Part 3

At the end of the study, we will [ask questions again, take measurements again, etc.]. Part 3 will take [duration].

**Are there risks or discomforts to consider?**

Discuss any discomforts or inconveniences that might apply. If there are no significant risks and any inconveniences are implied by the above discussion, this section can be deleted.

**Are there any benefits to joining the study?**

Discuss any direct benefits the individual might experience. If there are no personal benefits, this section can be deleted.

**Will I be paid to participate?**

***[Add in this language if participants are being paid. If you would like an exception to this requirement, please contact the Research Institute for an exception and document that exception in your IRB submission.]***

You will receive $xx for each study visit. If you complete all regularly scheduled visits, you may receive up to $xx. If you leave the study early, you will be paid only for the visits you completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

**[If applicable]** Reimbursement for travel expenses may be available. ***[Describe the criteria for reimbursement being available. Please note that reimbursements are different from study payments: they are not tax deductible; also, the participant must provide receipts.]***  All reimbursements will need to be pre-approved by the study team. You will be asked to keep your receipts in order to receive reimbursement.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

**Alternatively, insert a statement that there is no payment for participating in the study.**

**How will confidentiality and privacy be protected?**

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your study information will be labeled with your research ID number. The study team will keep a separate list that matches your name to the research ID number. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn’t have it.

***Add the required HIPAA Authorization language in the remainder of this section if protected health information is being used or created for the project.***

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. [PI name] and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

* Federal agencies that oversee human research (if a study audit is performed)

**Remove any of bulleted list below that does not apply:**

* Study partners, including [identify partnering institutions]
* [Funding source/sponsor]
* Business partners of the sponsor
* Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
* The FDA and similar groups in foreign countries [This bullet can be removed for studies that do not involve FDA-regulated products.]
* Other groups that help manage or provide services to support the study
* Ethics committees that review the study for other locations

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to [PI Name]. The mailing address is [PI Name], University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of [the study drug, device, treatment]. They are permitted to use and share information that was gathered before they received your cancellation.

**Consent**

Please talk to the research team if you have any questions about joining the study. If you have questions about the rights of research participants, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

If you agree to join, please sign and date below. You will receive a signed copy of this form.

Printed name:

Signature: Date