**BIOREPOSITORY 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.

The purpose of this study is to collect and store [blood, tissue samples, urine, cheek swabs, etc.] and medical information about people who [describe the qualifying condition]. This collection of samples and information is called a biorepository.

The biorepository will provide samples and information to researchers at KUMC and other institutions for future studies that [general description of the goals and possible topics of study (help diagnose, improve, treat, etc.) and what can be learned by studying these samples].

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

You are being asked to provide medical information and samples at [XX#] study visit[s].

Medical Information: Information will be collected from your medical records and from questionnaires (if applicable). Study records include personal information such as age, gender, family history, diagnosis, treatments, and medications (add other items as applicable such as lab results, x-rays, scans, etc.). Your information will be updated [discuss frequency] as long as you are a patient at KUMC.

Blood Samples: Up to XX tubes of blood will be taken and stored for future research. The sample will be collected when you are having blood drawn for your standard medical care [or discuss other timeframe]. [As applicable, discuss frequency of future blood draws.]

Other Specimens: (include an entry for each type of specimen) We will also request [a urine sample, saliva sample, or cheek cell sample (as applicable. Discuss frequency and process).

Tissue Specimens: Any tissue or body fluid that is removed during [a medical or surgical procedure] and is not needed for your medical care will be stored for research. No extra tissue will be taken for the purpose of this study. The leftover tissue would normally be thrown away.

**What types of research projects will be done?**

Your information and samples could be used for a variety of research projects about diagnosis and treating [disease, condition, etc]. Future projects might include genetic testing. Genetic testing studies pieces of DNA called genes. Genes provide the instructions needed to make our bodies work.

Genetic tests are changing rapidly, so it is not possible to exactly describe all the tests that might be performed. Because researchers won’t know who you are, the results of their tests will not be shared with you or your doctor. Results will not be put into your medical record.

If applicable, discuss the creation of cell lines. Contact the HRPP for suggested language.

The research could lead to discoveries or inventions in the future. Participants will not be paid if a commercial product is developed.

**What are the risks of the study?**

Research with information and samples can have risks. If you have any questions about the risks below, please talk to the study doctor.

*Risks of sample collection:*[Adjust sample language as applicable]

Taking blood may cause pain, bleeding or bruising. Rarely, taking blood may cause fainting or infection.

Risks of urine collection or cheek swabs are minimal.

The tissue collected for this study will be leftover and would normally be thrown away. There are no additional risks from tissue collection.

*Risks about confidentiality:*

There is a small risk of loss of confidentiality when personal information is used for research. Your information will only be used by study team members and approved researchers. No one’s name will be used when this research is published or presented. The privacy section below provides additional details.

*Risks of genetic testing:*

There may be risks to giving your samples for genetic research. A federal law called the Genetic Information Non-Discrimination Act, or GINA is in effect. This law does not allow insurers or employers to use genetic information to discriminate against you. The law does not cover other types of misuse by life insurance, disability, or long-term care insurance. To learn more about the GINA Law, please go to <https://www.eeoc.gov/laws/statutes/gina.cfmj>.

**How will my 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\_\_\_