Consent and Authorization to Participate in a Research Study

**KEY INFORMATION For {*TITLE OF STUDY}*:**

***Informed consent must begin with a concise and focused presentation of the key information on the reasons why one might or might not want to participate in the research. Include most crucial information from the potential participant’s perspective; must not exceed one page.***

We are asking you to choose whether or not to volunteer for a research study about \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*insert general description of study*}. We are asking you because\_\_\_\_\_ *{indicate if condition or circumstance makes person eligible for participation}*. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

**what is the STUDY ABOUT AND HOW LONG WILL IT LAST?**

***Briefly*** *describe the purpose of the study and the procedures to be followed in lay terms. For detailed descriptions, use the Detailed Consent and/or Appendices.*

By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation in this research will last about {*state in hours, days, months, years*}.

*If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness include the following:* The purpose of this research is to gather information on the safety and effectiveness of \_\_\_\_\_\_\_\_\_\_\_\_ *{state name of drug, device, etc.}. Specify FDA-approval status:\_\_\_\_\_\_\_\_ is/is not* approved by the Food and Drug Administration (FDA) *or* \_\_\_\_\_\_\_\_\_is approved by the Food and Drug Administration (FDA), but being tested for a different purpose.

**what are key reasons you might choose to volunteer for this study?**

State the most important reason(s) {i.e. potential benefit(s)} a person may want to volunteer to participate in this study? For a complete description of benefits, refer to the Detailed Consent.

**what are key reasons you might choose not to volunteer for this study?**

State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant’s perspective. This is generally NOT exclusion criteria unless a specific exclusion is likely to impact willingness to participate. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

If *alternative treatments/procedures are key to the participant’s choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists.* For a complete description of alternate treatment/procedures, refer to the Detailed Consent and/or Appendix.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

*Add the following for student volunteers:* As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).

**what if you have questions, suggestions or concerns?**

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Principal Investigator, PI}* of the University of Kentucky, Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*list department}* at {*PI contact information}*.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

**detailed consent:**

***The following detailed consent template includes sample language for many different types of research. remove text that does not apply to your research.***

***Instructions are italicized in blue font. Remove the instructions, unwanted text, and underlines and reformat the final form to fit the protocol.***

***More than a third of adults have basic or below basic health literacy. Use lay language and terminology throughout the document. Tools are available on the*** [***ORI Informed Consent Webpage***](https://www.research.uky.edu/office-research-integrity/informed-consentassent)***, including links to*** [***simple words and phrases***](https://plainlanguage.gov/guidelines/words/use-simple-words-phrases/)***;*** [***everyday words***](https://www.cdc.gov/other/pdf/everydaywords-060216-final.pdf)***; and*** [***standard risk language***](http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/05_-_Database/index.html)***. Check readability scores and use these tools to develop clear language that is appropriate for your subject population.***

*If the sole objective of the current study is to develop a research registry or data repository, use the* [***ORI Repository/Registry/Bank Template***](https://www.research.uky.edu/uploads/ori-f10170-form-c-med-and-hipaa-repository-registry-bank-word)*to create the consent form and obtain consent for future secondary use/sharing.*

***Optional Appendices:*** *Lengthy lists of examples, tables, decision tools, reference lists, or graphics may be best presented in an Appendix instead of paragraph text. If using appendices, state in the Detailed Consent when additional information can be found in an Appendix. Delete Appendices if not used.*

**ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?**

*State the reasons a participant could be excluded from participating (such as being a smoker, being under 18 years of age, being pregnant, etc.). Include only those events or conditions, which would* ***not*** *be pre-determined by a review of records or by the decision of an attending physician. Include those events/conditions of which the potential participant would ordinarily be aware.*

**WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?**

The research procedures will be conducted at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{state the general facility such as UK Medical Center, Sanders Brown Center on Aging, etc.}*. You will need to come \_\_\_ times during the study. Each of those visits will take about \_\_\_ *{state in minutes or hours}*. The total amount of time you will be asked to volunteer for this study is \_\_\_ *{state in hours/days}* over the next \_\_\_ *{state in days, months or years}.*

**what will you be asked to do?**

*Tell the participant what to expect.*

* *Give a timeline description of the procedures that will be performed, the drugs or devices that will be administered, all hospitalizations, and all outpatient visits. If you are providing a procedure illustration, visit schematic, or other reference to accompany descriptions of procedures and tests for studies, include in* ***Appendix: Study Visits/Procedures/Glossaries/Illustration.***
* *Answer the following for the participant:*
	+ *What is being performed as part of the research?*
	+ *For studies that also include clinical care, differentiate procedures being conducted for research versus those for standard of care.*
	+ *Clearly identify any procedures that are experimental.*
* *Provide a description of the randomization procedures, if applicable, and describe the chances of being assigned to any one group. Define randomization in simple language such as “by chance.”*
* *Add information regarding pregnancy testing for women of childbearing potential, if required, and actions that may be taken if the participant (or a participant‘s partner) becomes pregnant. Birth control measures required for the study may be listed here or if extensive, in an Appendix.*
* *If the research is regulated under the European General Data Protection Regulation (GDPR), reference any special categories of personal information explicitly. To determine what types of data are considered special under the GDPR, please consult the* [*UK GDPR Guidance*](https://www.research.uky.edu/uploads/ori-d1470000-uk-general-data-protection-regulation-gdpr-guidance)*.*
* *If this study involves genetic or genomic testing, include applicable language from the* ***Storing and Sharing for Future Use*** *section.*

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

*If there are risks to participation that are not already presented in the Key Information page, describe them for each investigational procedure, drug, device or biologic.* *The participant may more easily understand lengthy information about risks of therapy/procedures in the study if the information is presented in table form, graphic, or visual aid. If presenting risks in this format, include in* ***Appendix: Risks****.*

* *Group the risks into those that are expected, ranking them as rare, occasional, or often, and describe them as such.*
* *In lay terms, list* ***all reasonably*** *expected side effects and those that are life altering or potentially life altering, no matter how rare. For example, vision loss, allergic reaction, paralysis, etc.*
* *Provide equivalent exposure language for use of radioactive material or x-rays conducted for research – contact UK* Radiation Safety for dose estimates and lay language equivalents
(859) 257-7128  <https://ehs.uky.edu/radiation/>
* *Explain the ramifications of risks. For example, what will happen to the participant if liver enzyme tests indicate an abnormality?*
* *Add a statement that the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable if the participant is or becomes pregnant. Studies that present real and potential risks of fetal or reproductive harm should have a description of this risk. If the risk of fetal harm is not known, indicate so.*
* *If venipuncture is being performed as part of the research, include each of the following as a potential risk of that procedure: soreness, bruising, pain, infection, possible fainting, bleeding.*
* *Include significant risk of social, psychological, emotional, or financial harm (e.g., breach in confidentiality in sensitive research) and what steps will be taken to addresses these harms (e.g., referral to mental health services, follow-up care, etc.).*

*The risk section must also contain the following statement (the first two sentences may not be applicable for social science studies).* There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

**WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

We do not know if you will get any benefit from taking part in this study. However, some people have experienced \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{insert potential benefit, please note that payment to subjects are not considered a benefit; payment details should be described in the “reward” section below}* when \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{qualify when potential benefit experienced}.* However, if you take part in this study, information learned may help others with your condition.

***OR***

You will not get any personal benefit from taking part in this study.

**IF YOU DON’T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

If you do not want to take part in the study, there are other choices such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(If this is a medical treatment study: describe what would occur should the person choose not to participate, i.e., standard of care. Also, describe any other treatments that might be available. If including lengthy alternative lists or extensive reference information, use the* ***Appendix: Alternative Treatment******Examples/Options****. For instance, this section may reference categories of treatment while the Appendix**could list specific treatment names for reference.*

*If this is a social/behavioral study, describe whether or not there are any procedures the subject could participate in to receive the same level of benefit).*

***OR***

If you do not want to be in the study, there are no other choices except not to take part in the study.

**WHAT WILL IT COST YOU TO PARTICIPATE?**

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

TheUniversity of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

*Subjects should be informed of any additional costs that may result from participation in the research. Add study specific language here by* ***selecting appropriate options below:***

Therefore, these costs:

* will be your responsibility; ***or***
* will be paid by the sponsor *{insert sponsor’s name here};* ***or***
* the sponsor {*insert sponsor’s name here}* has agreed to pay $\_\_\_ of those costs; ***or***
* may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer’s willingness to pay these costs); ***or***
* may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid. (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570.)

Your insurer, Medicare, or Medicaid, may agree to pay for the costs. However, a co-payment or deductible may be needed from you. The amount of this co-payment or deductible may be costly.

**WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. *If you are collecting social security numbers, inform participants of this fact. Tell participants whether they can withhold their social security number and still participate and whether social security number is necessary in order to pay subjects.*

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. *{Insert description of procedure(s) used for protecting confidentiality of data, including paper records, computer records, jump drives and portable storage devices.}*

You should know that in some cases we may have to show your information to other people because {*insert circumstances in which the participant’s data could be shown or reported to others}.* *If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI’s summary sheet:* [*“Reporting Requirements for Diseases and Conditions in Kentucky”*](https://www.research.uky.edu/uploads/ori-e20000-reporting-requirements-diseases-and-conditions-kentucky-pdf)*.*

For example, the law may require or permit us to share your information with:

* a court or agencies, if you have a reportable disease/condition;
* authorities, such as child or adult protective services, if you report information about a child or elder being abused;
* authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

To ensure the study is conducted properly, officials of the Food and Drug Administration (*if applicable*), the National Institutes of Health (*if applicable*), the National Cancer Institute (*if applicable*), Department of Defense (*if applicable*), the University of Kentucky, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*indicate the sponsor’s name or any group/company that may have access to information}* may look at or copy pertinent portions of records that identify you.

*Add the following if the research is regulated under the European General Data Protection Regulation (GDPR) and third-party software will be used to collect data. Ensure the software is GDPR compliant:* We will be using \_\_\_\_\_\_\_\_, a data collection software. It is important to note that any data collection process undertaken through the use of third-party software comes with potential risks. Included among these risks is a potential breach of confidentiality. The study team will take all available precautions to prevent this from occurring, although we cannot guarantee that your identity will never become known.

*Add the following information if online data-collection applies to study:* We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

*Add the following information if REDCap is being used as a survey instrument for your research:* REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

*If the study has an* ***NIH Certificate of Confidentiality (CoC),*** *include the NIH CoC verbiage to your consent form. If not, delete the CoC heading and section.*

**Certificates of Confidentiality (CoC):**

*If your study has a Certificate of Confidentiality from the National Institutes of Health (NIH), add the verbiage below to your consent form:*

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

* you have requested us to provide, for instance, to your insurance company or doctor;
* to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
* about child or elder abuse, neglect, or harm to yourself or others; and
* about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study. By signing this consent you agree that your healthcare providers and associated staff affiliated, contracted with, or with access to records of the University of Kentucky (UK) may see your information from research studies and consider and use that information in the course of medical care and related activities.

***CoCs from other agencies:*** *Several non-NIH HHS agencies, including CDC, FDA, HRSA, and SAMHSA, issue Certificates of Confidentiality (CoCs). If you obtained a CoC from a non-NIH agency, use the suggested template language from the agency.*

**CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

*Information should be added here to describe any adverse effects on the participants’ health or welfare, gradual withdrawal or follow-up that may be requested if they decide to withdraw from the study. For example: Certain drugs may harm you if you stop taking them suddenly.*

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

* you are not able to follow the directions,
* we find that your participation in the study is more risk than benefit to you, or
* the agency paying for the study chooses to stop the study early for a number of scientific reasons.

*Include the following information if applicable:* The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

**ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?**

*Include the following information if participating in other studies could put your participant at risk:*

You may/may not *{specify}* take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

**WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?**

If you believe you are hurt or if you get sick because of something that is due to the study, you should call \_\_\_\_\_\_\_\_\_\_\_\_\_ {*PI or medical supervisor’s name*} at \_\_\_\_\_\_\_\_\_\_\_\_\_ *{provide phone number}* immediately.

*For* ***greater than minimal risk*** *research, add information for one (or a combination) of the following as a contact for participants to use in case of illness or injury during their participation in the study:*

* *a dedicated pager number;*
* *a dedicated cell phone number;*
* *other reliable 24-hour contact option at your discretion; and*
* *in addition to one or more of the above, as deemed necessary, referral to 911 for an emergency.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*PI or medical supervisor’s name*} will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm *{add study specific language by* ***selecting appropriate options below****}*.

* will be your responsibility; ***or***
* will be paid by the sponsor *(the only option if industry sponsored*) *{insert the sponsor’s name here},* with some exceptions. The exception could be your failure to follow instructions; ***or***
* may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer’s willingness to pay under these circumstances); ***or***
* may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

**WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive \_\_\_\_\_\_\_\_ for taking part in this study*. {If this is a monetary reward/payment, explain how this will be pro-rated should the participant choose to withdraw early. If this is not a cash payment, the IRB strongly suggests that the reward be given to the participant regardless of completion of the study.}*

*If applicable, provide the following statement:*

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

***OR***

You will not receive any rewards or payment for taking part in the study.

**WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?**

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

**will you be given individual results from the research tests?**

*Indicate whether or not clinically relevant individual results will be given to participant, and if so, under what conditions.*

Generally, tests done for research purposes are not meant to provide clinical information. We *{specify will or will not}* provide you with individual research results.

*If there is potential for incidental findings, describe how incidental findings will be managed and whether findings will or will not be communicated to participant.*

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*specify review by a special committee, an expert consultant*} to determine if it is in your best interest to contact you.

If so, \_\_\_\_\_\_\_ {*the repository, your primary/clinical care provider*} will contact you using the information you provided. With the help of a {*medical specialist, a genetic counselor}*, they will present possible risks or benefits of receiving the information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this, call \_\_\_\_\_\_\_\_\_\_\_ {*list person to contact*}.

***OR***

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family’s health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family’s health).

* Yes No \_\_\_\_\_\_\_\_\_Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to \_\_\_\_\_\_\_\_\_\_ {*provide phone and mailing address}*.

**will we contact you with information about participating in future studies?**

If you are planning to contact these research subjects in the future regarding their potential participation in additional research studies, their permission to do so is recommended. If you do not plan to contact these research subjects regarding participation in additional studies, DELETE this section. Please note that if you are planning on creating a subject pool, a separate IRB application should be submitted.

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to *{specify frequency}* times per year.

Do you give your permission to be contacted in the future by *\_\_\_\_\_\_\_\_\_\_\_*(insert investigator or staff) regarding your willingness to participate in future research studies?  **  Yes No Initials\_\_\_\_\_\_\_\_\_**

**WHAT ELSE DO YOU NEED TO KNOW?**

*This statement may not be applicable:* If you volunteer to take part in this study, you will be one of about \_\_\_\_\_\_\_ people to do so. *If applicable, you may add "..*.one of about \_\_\_\_\_ people to do so nationally, and one of \_\_\_\_\_\_ at the University of Kentucky"*.*

*If the PI is a student**they should disclose this fact, and, add the following sentence:* They are being guided in this research by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Advisor}.* There may be other people on the research team assisting at different times during the study.

## (Include if study has a data sharing plan to place data in large-scale national databases)

Science journals and agencies that fund research often ask researchers to share their data.  Sharing data lets researchers explore new questions and repeat studies.  Results of a research study become stronger when they are proven more than once. We may put data from you and other people that take part in the research, into scientific databases. The data may be kept in the large databases forever. Some databases are open to anyone on the internet.  Some limit access to approved researchers.  We will not include your name and other information that could identify you.  No one would know just from looking at the data that the information came from you.

*If the research is regulated under the European General Data Protection Regulation (GDPR), include the following. To determine whether the research is subject to the GDPR, see the* [*UK GDPR Guidance*](https://www.research.uky.edu/uploads/ori-d1470000-uk-general-data-protection-regulation-gdpr-guidance)*.*

The European General Data Protection Regulation (GDPR) provides individuals, whose data will be collected, certain rights. These rights include:

* The right to access, correct, or request that your data is removed from the study;
* The right to restrict processing of your data;
* The right to object to the processing of your data;
* The right to withdraw your consent w/out any penalty; and
* The right to complain about the data collection/handling process. For any complaints, please contact the University of Kentucky Data Privacy at cybersecurity@uky.edu or 859-257-4594 and/or the University of Kentucky Office of Research Integrity at 859-257-9428.

*Disclose what institution(s) (such as NIH, NCI, etc.) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. An example of such a statement would be:*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{name of institution/company}* is providing financial support and/or material for this study.

Include the following statement if the study has a potential for commercialization. The information or specimens that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

*Applicable FDA-regulated drug (including biological products) and device clinical trials must include, in the informed consent form, the following statement regarding clinical trial information being entered into a national clinical trial registry data bank:* A description of this clinical trial will be available on <http://www.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.

*For* [*NIH-funded clinical trials*](https://grants.nih.gov/policy/clinical-trials/definition.htm) *and other registered trials that do not meet the definition of an FDA applicable clinical trial:* A description of this clinical trial will be available on <https://www.clinicaltrials.gov/>. 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.

*Note, if the IRB determines that disclosure of financial interest is necessary to protect the participants’ rights and welfare, you may be asked to include a statement which informs participants of the investigator’s financial interests in the study (i.e. the source of funding and funding arrangements for the conduct and review of the research, or information about a financial arrangement of the investigator and how it is being managed).*

**will your information (or Specimen Samples) be used for future research?**

***OPTION 1: Include the following statement if you will NOT, keep, use and share information or specimens from this study for future use:***

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

***OR***

***OPTION 2: Include the following statement if at the end of the study, you will destroy all identifiers and keep, use, and share only de-identified data for future research:***

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. This means that no link or code to your identity will be kept.  After all identifiers have been removed, the information or samples may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

***If OPTION 1 or 2 is selected, DELETE* the OPTION 3: *FUTURE USE* section below.**

***OPTION 3: If you are keeping coded or identifiable information or specimens for future research, delete OPTIONS 1 and 2. Include OPTION 3, describing how identifiable information or specimens will be kept, used, and shared for future research.***

**STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:**

The researchers would like to store, use, and share your identifiable (*specify information and/or samples)* for future research without your additional consent. Having *information/samples* from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored *information/samples* to learn more about \_\_\_\_\_\_\_\_\_ (*cancer, diabetes, and other health problems*) or research additional scientific questions.

*(Specify if requesting current and future access to the medical record)*Researchers would like to have permission to look at your medical records from time to time *(or specify frequency)*. Researchers would collect general information related to your health such as test results, treatments, and doctor’s notes. The confidentiality section below provides details about how we will keep your information private.

*(Include for genetic studies)* Genetic studies help explain why traits (eye color, personality, etc.) or diseases are passed down in families. Results of genetic studies may also reveal information about your family members.  Researchers may use genetic material in your sample to learn about the role they play in heath and disease. Even if researchers do this type of research, the results will not be put into your health record.

*(Include if applicable)* Researchers may use your sample to create a “cell line” which is cells grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

*(Include if applicable)* Your cells may be used in laboratory studies to test treatments to see how well they work before using them in patients. Researchers may mix your cells with other human cells or implant them in laboratory animals such as mice.

*(Include for genomic analysis)*. Your complete set of your genetic information is called your “genome”. Your genome is completely unique to you.  Researchers may analyze sections or all of your genome. They may also analyze genomes from many different people to look for differences which may help predict what makes people more or less likely to inherit a trait or get a certain disease or condition.

*(Include for genomic data sharing)* To advance scientific discovery, researchers share genomic data.  Your genomic and health information may be put into scientific databases along with information from other people. Your name or information that could directly identify you will never be included. Researchers who want to study the information must apply for and get permission to use the data.  Summary results (trends or findings) may be placed in databases that are publicly available.

*Note: Consider providing subjects with a link to the Genomics Education Program* [*video tutorial*](https://www.genomicseducation.hee.nhs.uk/education/core-concepts/what-is-genomics/) *for more information.*

**WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?**

The information will be stored at *\_*\_\_\_\_\_\_\_\_\_\_\_ *{describe location/facility} \_\_\_\_\_\_\_\_\_\_\_\_\_\_ {indefinitely, for no longer than XXX years/months}*.

**ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?**

***Physical:***

There is no additional physical risk from collecting leftover tissue from a procedure that is being done as part of your clinical care.

***Include only if additional blood is being collected via venipuncture, for storage and future use:***

Risks associated with blood sampling are generally slight, but may include soreness, bruising, pain, infection, possible fainting, bleeding.

***Include only if additional tissue will be collected during a clinical procedure, for storage and future use:***

When we collect extra tissue during your procedure, we will limit the amount so that there is no significant increase in risk to you {*OR* *describe specific additional risks associated with additional tissue collection}*.

***Privacy and Social/Psychological:***

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

***Include if genetic or genomic testing is possible*:**

Even without your name or identifiers, genetic information is unique to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress. We do not know whether future technology will make it possible for someone to trace your genetic information back to you.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

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

Researchers will take careful steps to keep your information confidential.

*Describe confidentiality protections:*

*(Include if storing specimens/information with identifiers):* Researchers will store your identifiable information or samples, in a *{specify, locked freezer, password-protected database;* encrypted *file which changes it to another format to protect it from being accessed by anyone outside of the approved staff}*.

*(Include if coding specimens/information and storing identifiers elsewhere):* Researchers will remove your name or other direct identifiers from your information or samples. We will label your information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

**HOW WILL WE SHARE YOUR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?**

Your de-identified information or samples may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your information or samples with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

*Indicate if recipient researchers sign agreements to obtain information/specimens:* A researcher who receives your information or specimens will sign an agreement *(specify terms – to keep your information secure)*.

**what if you change your mind and want to withdraw your information or specimen samples?**

You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to \_\_\_\_\_\_\_\_\_\_ {*insert address}*.

Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.

**Will you receive any commercial profit from future research discoveries?**

The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

**Will you be given individual results from the future research tests?**

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

**If storing/sharing identifiable information or specimens for future use is optional, include the signature box below.**

**If storing for your future use is optional, include the signature box below, remove signature box.**

OPTIONAL FUTURE USE:

Do you give permission for your identifiable *(specify information and/or specimens*) to be stored, used, and shared for future research?  Yes  No Initials \_\_\_\_\_\_\_

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored or shared for future research.

***Include the following HIPAA Authorization ONLY if you are collecting protected health information under HIPAA and the IRB has not waived the HIPAA Authorization Requirement. If not, delete this page.***

**AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION**

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

**Your health information that may be accessed, used and/or released includes:**

* *List all of the protected health information[[1]](#footnote-2)\* to be collected for this study such as demographic information, results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures, as well as medical history. Also, include Medicare Health Insurance Claim Numbers (HICN), Social Security Numbers (SSN) and Employer Identification Numbers (EIN) if regulated by Medicare reporting provisions.*

**The Researchers may use and share your health information with:**

*Note: The information listed in this section should include all the agencies/researchers included in the consent form; however, the authorization may require additional information or more specific information than the consent form.*

* The University of Kentucky’s Institutional Review Board/Office of Research Integrity;
* Law enforcement agencies when required by law;
* University of Kentucky representatives;
* UK HealthCare and their representatives *{if applicable. You must include this item if you are providing financial compensation for study participation or obtaining lab results from UKMC}*;
* UK Health system (EPIC, the electronic medical records) and health systems outside of UK for which you have a patient relationship;
* *If your research falls under the purview of a government agency (e.g. FDA, NIH, etc.), list them in this section of the authorization form.*
* Investigational Drug Service (IDS) *{if investigational drugs are dispensed through IDS}*;
* Center for Clinical and Translational Science (CCTS) *{if CCTS staff are involved in the study}*;
* National Cancer Institute (NCI) *for cancer-related studies only*;
* *List any collaborators, outside laboratories, etc.*
* *If applicable – list the sponsor’s name and its agent(s) or government agency funding your research.*
* *List any other groups with whom the information may be shared.*
* *If applicable – a statement that the primary physician will be contacted if the researcher, in the course of the project, learns of a medical condition that needs immediate attention.*

*If reporting pregnancy is required by the Sponsor add the following language to the authorization form*: If you become pregnant anytime during the study or within \_\_\_\_ days after stopping the study drug, you must inform the study doctor. The study doctor must then report the outcome of your pregnancy to the Sponsor (and/or the FDA).

***OR***

*A separate authorization to release pregnancy information to the Sponsor may be required.*

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

* Current or future healthcare at the University of Kentucky;
* Current or future payments to the University of Kentucky;
* Ability to enroll in any health plans (if applicable); or
* Eligibility for benefits (if applicable).

**After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:**

* Send a written letter to: {*name and contact information}* to inform *{him/her}* of your decision.
* Researchers may use and release your health information **already** collected for this research study.
* Your protected health information may still be used and released should you have a bad reaction (adverse event).

*Optional item:* You will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you may have the right to access the information.

The use and sharing of your information has no time limit.

**If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky’s Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.**

***SAMPLE APPENDIX: Study Visits/Procedures/Glossaries/Illustration***

***If including tools to accompany descriptions of procedures in the Detailed Consent (e.g., study schematic, procedure list, approved birth control list, glossary or illustration), include below in lay language.***

***IF NOT, DELETE THIS APPENDIX***

**Appendix: Study Visits/Procedures/*Glossaries/Illustration****{specify what is included in the title}*

*Example of Study Visit Schedule:*

|  |  |  |
| --- | --- | --- |
|  |  | STUDY PERIOD |
|  |  | Enrollment | Treatment | Follow-up |
| TIMEPOINT | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Screening to see if you qualify | • |  |  |  |  |  |  |  |  |  |
| Informed consent | • |  |  |  |  |  |  |  |  |  |
| TREATMENT |  | • |  |  |  |  |  |  |  |  |
| Study Drug |  |  | • | • | • | • |  |  |  |  |
|  Pill Count |  |  | • | • | • | • |  |  |  |  |
| Counseling  |  |  |  |  |  |  | • | • | • | • |
| TESTS |  |  |  |  |  |  |  |  |  |  |
| Safety Labs |  | • |  |  |  | • |  |  |  | • |
| Study Labs |  | • |  |  |  | • |  |  |  | • |
| Brief Physical Exam (Blood pressure, pulse, etc.) |  | • |  |  |  | • |  |  |  | • |
| Problems/Complaints |  |  | • | • | • | • | • | • | • | • |

***SAMPLE APPENDIX: Risks***

***If a lengthy list, table, or infographic will be used to present risks, include below. Use lay language and include implication of potential risks.***

***IF NOT, DELETE THIS APPENDIX.***

**Appendix: Risks**

*Example of risk incidence table:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Possible Risk/Side Effect** | **How often has it occurred?** | **How serious is it?** | **Can it be corrected?** |
| Rash | It occasionally occurs | It usually involves the face and arms and may cause scratching | It will go away with treatment |
| Liver damage | It is extremely uncommon | Very serious | The damage is permanent and can affect the rest of your health |
| Skin discoloration | It is uncommon | It will not impact your overall health | No |

***SAMPLE APPENDIX: Alternative Treatment Examples/Options/References***

***If listing additional detail or examples of alternative treatments, or other information useful for participant reference, include below.***

***IF NOT, DELETE THIS APPENDIX***

**Appendix: Alternative Treatment Examples/Options/References** *{specify what is included in the title}*

*Example: alternative treatment listing*

Alternative Cholesterol Lowering Medications Include:

* atorvastatin (Lipitor),
* fluvastatin (Lescol, Lescol XL),
* lovastatin (Mevacor, Altoprev),
* pravastatin (Pravachol),
* rosuvastatin (Crestor),
* simvastatin (Zocor), and.
* pitavastatin (Livalo).

**informed consent signatures**

*Include the following if this study may enroll individuals under supervision of the Kentucky Department of Corrections (DOC) including: inmates, parolees, or individuals likely to be incarcerated by the DOC:*

If you are under the supervision of the Kentucky Department of Corrections (DOC), (including prisoners, parolees, state probationers or individuals awaiting sentencing for felony convictions), please note:
The DOC requires researchers to provide the DOC with the name of participants and the title of the research study. By agreeing to be in the study, you are allowing the researcher to provide your name and the study title to the DOC. The researcher will not share any of your research data or confidential information with the DOC. The DOC may ask you to sign a separate consent form that verifies that you are volunteering for a study that is not a part of the DOC. If you do not want to sign the DOC consent form, you should choose not to participate in this study. If you chose **not** to sign the DOC consent, we would have to withdraw you from this study.

**This consent includes the following:**

* **Key Information Page**
* **Detailed Consent**
* ***If Appendices are used, list here***

**You will receive a copy of this consent form after it has been signed.**

|  |
| --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature of research subject** *or, if applicable,* **Date***parent or guardian* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Printed name of research subject** *or, if applicable,**parent or guardian*  |
| *Remove this shaded section if not seeking IRB approval to obtain consent from a legally authorized representative*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature of Legally Authorized Representative Date**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\*Printed name of research subject’s legal representative* *\*If applicable, please explain Representative’s relationship to subject and include a description of representative’s authority to act on behalf of subject:*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_Printed name of [authorized] person obtaining informed consent and HIPAA authorization *(if HIPAA applies)* Date*Add other desired signature lines (e.g. investigator) per sponsor request or investigator preference.* |

1. **\****Name, Address, Dates Directly Related to an Individual, Telephone/Fax Number, E-mail/Internet Protocol or Web URL Address, Social Security Number, Medical Record or Health Plan Number, Account Number, Certificate of License Number, Photographic Images, Vehicle Identifiers, Device Identifiers, Biometric Identifiers, Any Other Unique Code* [↑](#footnote-ref-2)