Instructions: Because there is extensive variation in the design and operation of research repositories, a "one size fits all" template is not feasible. Investigators banking biological material for an individual study or research repository are directed to the document: **"Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use" [PDF].** The document presents optional approaches for the consent process, issues for consideration (that may or may not apply), and sample template language.

The following is a pre-fabricated template including sample language from the issues document. While this version is more user-friendly from a technical perspective, investigators are encouraged to first refer to the issues document above to customize a form and process that fits the unique characteristics of the repository or banking study.

Instructions, examples and optional wording are italicized. Reformat and remove the instructions, unwanted text, and underlines from the final form. Use lay language and terminology throughout the document and consider use of educational tools such as glossaries, illustrations, etc to simplify the consent form and enhance the consent process.

Sample Consent to Participate in a Research Repository or Individual Study Banking Material for Future Use

WHAT IS THE PURPOSE OF THE *BANK*?

The purpose of the bank is to collect and store samples of (*tissue, blood, and/or other biologic specimens*), along with health information for research purposes. Researchers can then use the stored materials for future research studies to learn more about (*cancer, diabetes, and other health problems*). The bank provides a ready supply of samples, so researchers do not have to look for donors for each new study.

The bank will enroll _____(*number*) of participants.
OR
The goal of the bank is to ask patients _____ (*specify pool of potential participants*) if they would like to participate. Having samples from many people allows the researchers to identify trends and discover better ways to diagnose, prevent, and treat many conditions.
The researchers who obtain your samples from the bank may use the genetic material (genes, DNA, RNA) in your sample to learn about the role genes play in heath and disease. Results of genetic studies may also reveal information about your family members.

WHERE WILL SAMPLES AND INFORMATION BE STORED AND FOR HOW LONG?

The samples and information will be stored at _____ *(describe location/facility)* _____ *(indefinitely, for no longer than XXX years/months)* or until they are all used up.

WHAT WILL THE BANK COLLECT AND STORE FOR RESEARCH?

If collecting leftover tissue:
We would like to keep some of the tissue or sample that is leftover from a procedure that you are already having as part of your clinical care, such as a blood draw, surgery, or biopsy. Your tissue or sample will always be used first to help make clinical decisions about your care or health.

If collecting extra tissue from a clinical procedure:
We would like to collect ____ (specify amount) of extra tissue from your (*specify procedure, surgery, biopsy*) that you are already having as part of your clinical care. Your tissue or sample will always be used first to help make clinical decisions about your care or health. The extra tissue will be kept for research.

If collecting blood or other specimens:
We would like to collect (*draw x tube(s), about X tablespoons) of blood; a sample of urine, saliva, hair, etc.*) for use in future research.

Specify if collecting information from participant such as a health questionnaire or medical history:
We also would like (*to interview you and/or for you to answer some questions on a form* about your *health, medical condition, medical history*, and/or *quality of life*. You can skip any question that you do not want to answer. (*If bank protocol involves repeated contacts to update information*) We will contact you no more than once a year to update this information.

Specify if requesting current and future access to the medical record:
We also would like to have permission to look at your medical records from time to time. We would collect general information related to your health such as test results, treatments, and doctor's notes. Medical records may also include psychiatric, genetic, HIVAIDS, alcohol/substance abuse information. The confidentiality section below provides details about how we will keep your information private.

WILL YOU BE CONTACTED ABOUT FUTURE RESEARCH?

Neither the bank nor researchers who access samples or information from the bank will contact you about future research. If you wish to participate in research studies, you may find information at http://www.ccts.uky.edu/ccts/participate-research.

HOW WILL THE BANK SHARE SAMPLES AND INFORMATION WITH OTHER RESEARCHERS?

Your sample or information may be shared with University of Kentucky (UK) researchers and researchers outside of UK. Researchers may contact the bank to request permission to use samples or information for their studies. An oversight committee will review the researcher's qualifications and proposed research. The committee will also determine if any additional review or approval is necessary.

If plan includes sharing only de-identified sample/information:
The bank will remove all information that could identify you such as your name, address, medical record number, etc, before sharing with researchers. *Include if applicable:* The *bank* will use _____ (*a process, software, barcodes*) to match your samples with your medical information without releasing your identity. The researchers will sign an agreement promising not to try to use any of the sample or information to identify you. The bank will not share information that could identify you without your permission.

Large-Scale Data Sharing:
Researchers can do studies that are more powerful when they share with each other the data or information they get from studying human samples. Information from analyses of your samples and your medical information may be put into scientific databases available on the Internet, along with information from other research participants. Your name and other information that could identify you will not be included. Therefore, no one would know just from looking at the data that the information came from you.

Genome Wide Association Studies:
Include if recipient investigators will be submitting data generated from NIH-supported and NIH-conducted research to GWAS:
If "open access": Anonymous information from the analyses may be put in a completely public database, available to anyone on the Internet.
If "restricted access": Your coded medical information and information from more detailed analyses of your coded samples may be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from Data Access Committee at the National Institutes of Health (NIH). Identifying information such as your name, address, telephone number, or social security number, will not be put into the scientific databases.

WILL YOU BENEFIT FROM TAKING PART IN THE (*BANK*)?

There is no direct benefit to you. The knowledge gained from research on your sample may help others in the future.

ARE THERE RISKS FROM TAKING PART IN THE (*BANK*)?

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 if additional blood is being collected as part of the research via venipuncture:
Risks associated with blood sampling are generally slight, but may include soreness, bruising, pain, infection, possible fainting, bleeding.

Include if additional tissue will be collected during a clinical procedure:
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 information stored in the bank. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Include if genetic testing is possible:
Even without your name or identifiers, genetic information is unique to you making it possible for someone to trace it back to you. The results of genetic research apply to both you and your family members. In some cases, it could be used to make it harder for you to get or keep a job or insurance. Genetic information could be used in ways that could cause you or your family distress.

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 already known genetic disease.

Unknown:
There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?
(*Include this section for greater than minimal risk research or research involving invasive procedures to collect specimens, or collection of <u>extra</u> tissue during a clinical procedure. Otherwise delete.)*

If you believe you are hurt or if you get sick because of something that is due to the study, you should call _____ (*PI's or medical supervisor's name*) at _____ immediately. *Include information for one (or a combination) of the following as a contact for subjects to use in case of illness or injury during his/her participation in the study:*

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

_____ (*PI's or medical supervisor's name*) will determine what type of treatment, if any, that 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.
The medical costs related to your care and treatment because of research related harm *(add study specific language by selecting appropriate options… e.g.,* will be your responsibility; or will be paid by the sponsor (*only option if industry sponsor and industry trial*) *(insert the sponsor's name here)* for medical expenses incurred by treating injuries that directly result from participating in the study, with some exceptions. The exceptions are instances such as your failure to follow the sponsor's directions or the investigator's failure to follow the sponsor's directions; 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 from you may be required 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 substantial.

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

HOW IS YOUR PRIVACY AND CONFIDENTIALITY PROTECTED?

The bank will take careful steps to keep your information confidential. *(Insert description of procedure(s) used for protecting confidentiality of data including paper records, computer records, jump drives and portable storage devices).*

We will remove information such as your name or other direct identifiers from your sample and medical information. We will label your samples and information with a code. The coded sample and information will be _____ (*describe security of storage, e.g., a locked freezer that is located behind locked doors, a password protected database*). Only select bank staff will have access to the list that links the code to you. The bank staff members sign an agreement to keep your identity a secret to the extent allowed by law. In very unusual cases, staff at the bank may be required to release your identifiable medical and research information in response to an order from a court of law.

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 that may have access to information)* may look at or copy pertinent portions of records that identify you.

Include if you have obtained a Certificate of Confidentiality (if applicable):
To help us protect your private information, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions:

- auditing or evaluation of federally funded projects;
- inspection by the federal Food and Drug Administration (FDA)(if applicable);
- or voluntary releases such as where you have shared your information, given written consent to allow access to your information, or disclosed abuse or a situation requiring reporting to authorities to prevent harm to yourself or others.

DOES TAKING PART IN THE BANK COST ANYTHING?

There will be no additional costs or charges to you for taking part in the bank. You will not need to pay for sample collection or blood test done just for the bank.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THE BANK?

You will receive _____ for donating your sample or information to the bank.

OR

You will not be paid for donating your sample or information to the bank.

The sample and information that you are donating 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 RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. Because the researchers will not have access to information that identifies you, the research findings will generally not be provided to you. There is a slight possibility that during a research project, a researcher 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 bank, your primary/clinical care provider*) will contact you at the contact 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_____.

OR

Do you give permission for (*the bank, researchers*) to contact you with information 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 bank phone and mailing address*).

Are there other choices if you do not want to participate in the repository?

If you do not want to take part in the repository, there are no other choices except not to take part. Your decision will not affect your current or future medical care.

WHAT IF YOU CHOOSE NOT TO PARTICIPATE OR CHANGE YOUR MIND AND WANT TO WITHDRAW FROM TAKING PART IN THE BANK?

Taking part in the bank is voluntary. Choosing not to take part will not affect your care or cause you to lose benefits to which you are entitled. You may withdraw your permission to continue taking part in the bank at any time. To do so, you must send a written withdraw request to the bank at _____ (*insert address)*. The bank will destroy any remaining samples and information that has been stored. In addition, it may be possible for the bank to destroy the code that links you with your sample and medical information. However, the samples and information that has already been shared with other researchers or placed in shared databases cannot be withdrawn.

WHAT IF YOU HAVE ADDITIONAL QUESTIONS, SUGGESTIONS, CONCERNS OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the bank, please ask any questions that might come to mind now. You may contact the _____ at _____ for questions in the future. If you have any questions about your rights as a volunteer, contact the University of Kentucky Office of Research Integrity staff, between 8:00 am and 5:00 pm, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

OPTIONAL SUB-STUDY:
(*If banking is an optional sub-study of a research protocol, incorporate applicable text from sections above in the main study consent form and format to allow subject to opt-in or opt-out of participating.)*
In addition to the main study, you are being asked to volunteer for an optional sub-study that involves (s*elect and include statements addressing applicable issues from categories above).*

After reading and considering the above information, indicate below if you give permission for (*insert investigator or sponsor)* to keep your (specify - *tissue/blood sample, DNA and/or medical/health information*) at _____ (*insert location*) until they are used up but no longer than_____ (*insert time frame*) years for use in future research to learn more about how to prevent, detect, or treat _____ (*insert name of disease*)?

Remember your participation in this sub-study is optional. You can still be in the main study even if you do not wish to participate in this sub-study.
If you answer yes, you also give your authorization for your accompanying health information to be used and disclosed along with the blood (*and /or tissue*).

☐ Yes, I choose to participate in the optional banking sub-study. ____Initials

☐ No, I choose not to participate in the optional banking sub-study. ___Initials

(Unless the HIPAA Authorization requirement is waived by the IRB, include HIPAA authorization language for use and disclosure of Protected Health Information.)

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. Protected Health Information is defined as any of the *HIPAA recognized identifiers in combination with health information.

Your Protected Health Information that may be accessed, used and/or released includes:

- (*List all of the protected health information* to be collected for this protocol/bank such as demographic information, results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures, medications, treatment notes 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 bank may use and share your Protected 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 Hospital if applicable. You must include this item if you are providing financial compensation for study participation or obtaining lab results from UKMC.)*
- *(If your research fall under the purview of a government agency (i.e., FDA, NIH, GWAS, 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 involved in the study.)*
- *(National Cancer Institute (NCI) for cancer related studies only)*
- *(University of Kentucky Researchers and Researchers outside of the University of Kentucky who are authorized via written agreement with the bank.)*
- *(List any collaborators or outside laboratories),*
- *(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 a result or incidental finding that may impact your (or your family's) health is discovered, the finding will be reviewed by a committee to determine if you should be contacted. Your primary physician or healthcare provider, a genetic counselor, or medical specialist may also be consulted to review the finding.*

* 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

The bank agrees 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 would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research bank if you do not sign this form. If you decide not to sign the 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)
- Eligibility for benefits (if applicable)

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

- You will send a written letter to: (*name and contact information)* to inform the bank of your decision.
- Researchers may use and release your health information **already** obtained from the bank.
- Your protected health information may still be used and released should an individual research result or incidental finding be discovered that could affect you or your family's health.

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 8:00 am and 5:00 pm EST, Mon-Fri at: (859) 323-1184.

You are the participant or are authorized to act on behalf of the participant. You have read this information, and you will receive a copy of this form after it is signed.

When developing the consent/authorization form, please format to ensure the signature lines fall on a page containing text.

_____ _____
Signature of research subject (*if applicable:*) Date
or *research subject's legal representative

_____ _____
Printed name of research subject (*if applicable:*) Representative's relationship to
or *research subject's legal representative research subject

*(*If, applicable)* Please explain Representative's relationship to participant and include a description of Representative's authority to act on behalf of participant:

_____ _____
Name of [authorized] person obtaining informed consent/HIPAA authorization Date

_____
Signature of Principal Investigator or Sub/Co-Investigator