University of Kentucky Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

Informed consent for repositories and specimen banking is typically broad to allow for a wide range of potential future uses in research. However, the consent document should be specific enough to inform participants about concepts such as unspecified future research, unlimited medical record access, incidental findings, and large-scale data sharing.

Repositories have used a number of consent approaches to enhance donor comprehension, autonomy, and personal control over future use of donated material. Repositories may choose a tiered approach to allow participants to consent to select uses as long as systems are in place to ensure participant's wishes are followed. Another approach involves a simplified consent containing key issues, used in conjunction with supplemental material such as glossaries to define terms or FAQs to reiterate concepts. For instance, the consent could present implications of genetic testing, while a glossary could define and provide background information on the role human genes play in health and disease. Dynamic consent is a novel approach using modern communication strategies such as ongoing, interactive web-based consent.

Ultimately, research conducted by recipient investigators who access material from the repository must be consistent with the uses described in the bank protocol and consent form.

The following categories address issues and points to consider when designing an informed consent document for a research repository or a study that involves specimen banking for future use. Sample language, addressing issues common to general research repositories, follows each category. The categories are grouped to ensure inclusion of informed consent elements required by federal regulations. Studies that involve greater than minimal risk or invasive procedures to collect specimens specifically for research are directed to use the injury and compensation language from the standard UK Medical Consent Template.

Because there is extensive variation in the way banks and repositories operate, a "one size fits all" template is not feasible. A pre-fabricated, sample repository template is available on the UK IRB forms webpage, however investigators are advised not to use the template verbatim, but consider all of the following issues and customize the final consent form to fit the unique characteristics of their repository or their study that involves specimen banking.

Using the sample template language:

- *For simplicity, the word "bank" is used in the sample language to represent a repository, and the word "sample" is used to represent a tissue sample, specimen, body fluid, etc.*
- *Customize the language to describe the unique characteristics of the repository.*
- *Instructions, examples and optional wording are italicized.*
- *Where optional wording is provided, choose the applicable version and delete what is not applicable.*
- *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. Examples are available at the following links: Beskow, 2010 Duke Biobank FAQ; National Cancer Institute Biorepositories FAQ; A Guide to Your Genome; Genomic Data Sharing Glossary;*
- *Reformat and remove the instructions, unwanted text, and underlines from the final form.*

If use is for an individual investigator banking specimens as an optional sub-study:

- *Choose applicable statements from each category below and combine in one Optional Sub-Study Section that may be incorporated in the full research consent form. (See Optional Sub-Study section).*

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Purpose of Research Repository

- Inform participants of the purpose of the research repository.
- If applicable, provide a description of the types of research that may be conducted.
- Inform participants of all material that will be collected and maintained in the repository (e.g., leftover tissue, specimens, medical history, and health related questionnaires, current or future medical record information).
- If applicable, inform participants that samples may be used for genetic research. Provide lay descriptions of genes, genetic material, genomic or phenotypic information. You may provide supplemental education materials such as brochures, glossary of terms, etc.
- Indicate the (number) of participants OR state specific pool of potential participants (e.g., patients seen at a particular facility, patients with a certain diagnosis, etc.).
- Parental permission must have been obtained in order to use newborn dried blood spots collected on or after March 18, 2015 for federally funded research.

SAMPLE TEMPLATE LANGUAGE

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.

Duration and Location of Storage

- Inform participants how long sample will be stored; indicate if indefinite.
- Inform participants of the physical location of the bank.

SAMPLE TEMPLATE LANGUAGE

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.

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Procedures

- Describe procedures for obtaining specimens and information.
- Indicate if requesting unlimited access to medical records (which may include psychiatric, genetic, HIVAIDS, alcohol/substance abuse information) or if collecting medical information from participant.
- Indicate if collecting only samples leftover from clinical procedures.
- Specify if study involves collection of tissue solely for research purposes (e.g., collecting extra tissue from a biopsy for research). Note: Include injury and compensation section from the standard UK Medical IRB consent template.
- Inform participants of conditions under which data & specimens will be released to recipient investigators (e.g. de-identified, direct or indirect identifiers).

SAMPLE TEMPLATE LANGUAGE

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.

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Sharing of Material, Secondary Use, and Future Use by Recipient Investigators -

- Inform participants how often and for what purpose they will be re-contacted (if applicable) or give participants option to indicate if willing to be re-contacted.
- Participants may want to limit use of sample, (tiered consent). Use "opt-in", "opt-out" boxes where the bank protocol offers options for participants.
- Indicate plans for sharing material/data (e.g., UK researchers, researchers outside of UK).
- Generally, personal identifiers may not be released to recipient investigators. Indicate if samples will be stripped of identifiers prior to sharing with researchers.
- Describe the process for obtaining a determination regarding whether secondary use involves "human participant research" which requires IRB review.
- Instructions related to genomic data sharing are provided in the next section.

SAMPLE TEMPLATE LANGUAGE

Will you be contacted about future research?

Neither the bank or 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 www.ukclinicalresearch.com.

SAMPLE TEMPLATE LANGUAGE

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.

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NIH Genomic Data Sharing (GDS):

NIH funded projects that generate large-scale genomic data have specific sharing requirements under the NIH Genomic Data Sharing policy. Investigators who intend to use research or clinical specimens collected or cell lines created after January 25, 2015, to generate genomic data may only do so with consent, even if the data are generated from specimens that are de-identified (see NIH GDS Consent Guidance). NIH expects investigators to obtain consent for participants' genomic and phenotypic data (which may include some clinical information) to be used for future research purposes and to be shared broadly through databases. The databases may be generally accessible to the public (unrestricted access) or accessible only with the permission of governance committees or other processes (controlled access). The consent needs to inform participants about large-scale genomic data sharing and explain whether the data will be shared via unrestricted- or controlled-access databases, or both.

SAMPLE TEMPLATE LANGUAGE

Large-Scale Data Sharing:
Genomic data is information about a genome which is a person's complete set of DNA. DNA stores messages or codes. Codes strung together are known as 'genes'. Genes carry information that is passed on to future generations. Researchers can do studies that are more powerful when they share with each other the data or information they get from studying human genomes. Data obtained from analyzing your genomic information and your medical information may be put into scientific databases 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.

Unrestricted access database:
The information from this study will be freely available in a public, unrestricted database that anyone can use. [For example], the public database will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

Controlled access databases:
Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you.

Additional samples including population specific language is available from the NIH National Human Genome Research Institute

Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

Benefits

- Inform participant of no direct benefit or of uncertainties regarding benefits.
- Include other potential benefits as appropriate, (e.g., advancement of knowledge; clinical relevance to individual, family, or society as a whole.

SAMPLE TEMPLATE LANGUAGE

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.

Risks

- Social Risks: Breach of confidentiality could impact insurability, employability, reproduction plans, family relationships, immigration status, paternity suits, and stigmatization, if applicable.
- Psychological Risks: Address potential for distress from breach of confidentiality or impact of learning results; impact if no effective therapy exists; psychological stress for family members.
- If applicable, inform participants of federal privacy protections such as the Genetic Information Nondiscrimination Act (GINA), which generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against participants based on their genetic information.
- Physical Risks: Physical risks associated with collecting samples for research purposes or risks from collecting extra tissue during a clinical procedure.
- Unknown Risks: Participants should be informed that there may be risks that at this time are not known.

Examples of Variables Affecting Risks

- Will identifiers be linked directly or indirectly to the samples?
- Are safeguards for protecting privacy and maintaining confidentiality adequate?
- Has the repository obtained a HHS approved Certificate of Confidentiality?
- Will the repository be collecting more tissue than needed for clinical purposes?
- Will specimens be used for genetic research?
- What is the current state of technology with respect to the planned genetic testing?
- If genetic testing is anticipated, will participants be informed of results of test?
- Could publishing results of pedigree studies, lead to identification even when names or identifiers are withheld?
- Will both genomic and phenotypic data be collected? What safeguards are in place to protect the data?

Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

SAMPLE TEMPLATE LANGUAGE

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.

Injury and Compensation

- If study is greater than minimal risk or involves invasive procedures to collect specimens or extra tissue specifically for research, use applicable language from the standard UK Medical Informed Consent Template.

Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

Confidentiality and Privacy

- Address procedures for protecting privacy of participants and maintaining confidentiality of data.
  - Explain if material will be collected and stored with direct identifiers, with no identifiers, or with codes that provide a confidential link to identifiers.
  - Describe plans for physical & electronic security of data/sample.
  - If data are going to be collected and/or stored electronically, refer to the suggested procedures in the guidance document, *"Confidentiality and Data Security for Electronic Data"*.
  - Indicate if a Certificate of Confidentiality has been obtained.
  - Indicate if recipient investigators will sign an agreement prohibiting attempts to re-identify participants.
- Address limits to confidentiality (e.g., who will have access and under what circumstances).
  - Indicate if designated repository staff will have access to identifiable medical record information.
  - Indicate whether third parties (e.g., officials, administrators, sponsors) would have access.

SAMPLE TEMPLATE LANGUAGE

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*), 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.

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Payment, Costs, and Commercialization

- Inform participant of any financial compensation or costs of participation not covered in study such as the costs of genetic counseling or psycho/social counseling (if applicable).
- Inform participants if research could lead to commercially valuable product.
- What financial gain, if any, the participant would receive from any inventions/patents resulting from use of specimens.

SAMPLE TEMPLATE LANGUAGE

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.

Significant New Findings: Participant Access to Individual Research Results or Incidental Findings Including Genetic Data

- Inform participants regarding what results or incidental finding will be offered to participants.
- Indicate if findings will be reviewed to determine if appropriate to return.
- Define incidental findings, if applicable.
- Inform participants if results will not be provided and explain why.
- If findings are to be disclosed, describe disclosure procedures (e.g., genetic counseling).
- If findings are to be disclosed, explain implications of making results or incidental findings available.
- Allow participants to opt in or out of receiving results or future findings with this consent, or indicate if participants will be contacted and offered a “result-specific” consent in the event that a result or finding is deemed returnable. A result-specific consent provides the implications or ramifications of receiving the result or incidental finding that has been discovered. An example of a single-subject, result-specific informed consent is available at http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#Specimen.

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SAMPLE TEMPLATE LANGUAGE

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*).

Alternatives

- One alternative is not to participate or provide specimen to repository.
- Indicate if other opt-in or opt-out choices are offered.

SAMPLE TEMPLATE LANGUAGE

If you don't want to take part, are there other choices?

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.

Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

Optional Sub-Study: Additional considerations if request to bank material for future use is an optional part (sub-study) of another study.

- Modify language to specify the request is on behalf of an individual investigator or research sponsor.
- Address all applicable issues above when developing language for optional banking sub-study.
- Indicate that participation is not required in order to participate in the main study. Include opportunity to "opt-in" and "opt-out" of participating.

SAMPLE OF TEMPLATE LANGUAGE

Optional Sub-Study:

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

Voluntary Participation and Withdrawal from the Repository

- Inform participants that participation is voluntary and refusal imparts no loss of entitled benefits.
- Inform participants whether they may in the future request samples be destroyed.
- Inform participants of procedures for subsequently requesting that samples/materials be destroyed, or
- Inform participants of procedures for subsequently requesting that identifiers be removed from materials (if applicable).
- Describe any limitations on ability of participants to withdraw data or samples (e.g. specimens may not be able to be retrieved once they are distributed).

Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

SAMPLE TEMPLATE LANGUAGE

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.

Who to contact with questions, concerns, etc?

- Inform participants who to contact for questions or issues related to the repository.
- Inform participants who to contact regarding their rights as a research participant.

SAMPLE OF TEMPLATE LANGUAGE

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.

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HIPAA

- 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, 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.)*
- *(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

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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 (*insert may or will)]* 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) release or use 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.
- You may not be allowed to participate in the bank.

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 participant or *research participant's legal representative — Date

_____ _____

Printed name of research participant or *research participant's legal representative — Representative's relationship to research participant

*(*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

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References

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Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use

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