Sample Repository/Registry/Bank Consent

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| The following is a Sample Consent Template for a Research Repository (e.g., specimen bank, data registry) in which the purpose is to collect, manage, and share material or information for future research.  Because there is extensive variation in the design and operation of research repositories, a “one size fits all” template is not feasible. The template includes sample language for many different bank/registry operations. REMOVE TEXT THAT DOES NOT APPLY  Before submitting a proposal for a Research Repository, investigators are encouraged to first review the following guidance as applicable:   * UK Research Biosample Bank Guidance [D129.0000] [[PDF](https://www.research.uky.edu/uploads/ori-d1290000-uk-research-biospecimen-bank-guidance-pdf)] * UK Research Registry Guidance [D130.0000] [[PDF](https://www.research.uky.edu/uploads/ori-d1300000-uk-research-registry-guidance-pdf)]   Absent scientific justification, the establishment of multiple independent repositories collecting duplicate material increases the risk of tracking errors due to variability in practices and creates confusion on behalf of participants. |

***The following sample template includes consent language for Research Repositories, Banks, or Registries,* which will collect, manage, and share material or information for future research.**

* *Select and use the applicable term (i.e., registry, bank, repository) or title throughout the document.*
* *Remove text that does not apply to your research.*
* *Instructions and text options to select are italicized in blue font. Remove the instructions and reformat the final form to fit the repository operations and practices.*
* *Use lay language and terminology throughout the document and consider use of educational tools such as glossaries and/or illustrations to simplify the consent form and enhance the consent process. The following tools may be useful in creating an understandable document:* 
  + [Everyday Words for Public Health Communication (Centers for Disease Control and Prevention (CDC))](https://www.cdc.gov/other/pdf/everydaywords-060216-final.pdf)
  + [Use Simple Words and Phrases](https://plainlanguage.gov/guidelines/words/use-simple-words-phrases/)
  + [Informed Consent Language (ICL) Database (National Comprehensive Cancer Network (NCCN))](https://www.nccn.org/icl/default.aspx)
  + [Alternative Wording Suggestions](https://prism.kpwashingtonresearch.org/documents/PRISM_alternative_word_list.pdf)
  + [NIH Talking Glossary of Genetic Terms (National Institutes of Health](https://www.genome.gov/glossary/index.cfm?id=77)
* *BEGIN WITH KEY INFORMATION: The document must begin with “a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons* ***why one might or might not want*** *to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”*
* Use the[Consent\Assent Checklist](https://www.research.uky.edu/uploads/ori-o1-qi-consent-checklist-pdf) to ensure you have included the general requirements and federally required elements of informed consent.

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Consent and Authorization to Participate in a Research Study

**KEY INFORMATION FOR Research *(Specify Title of bank, registry)***

We are inviting you to take part in *(specify repository, bank, registry, throughout).* We are asking you because\_\_\_\_\_ *{indicate if condition or circumstance makes person eligible for participation}*. This page gives you key information on why you might or might not choose to participate. Detailed information follows this page. As we review both sections with you, ask questions that come to mind now. If you have questions later, contact the investigator in charge of the *bank/registry* at the information below.

**WHAT IS THE PURPOSE OF THE *(TITLE OF BANK OR REGISTRY)*?**

The purpose of the *bank/registry* is to collect and store *(specimen samples, information)* from *(specify target number of subjects, e.g., hundreds)* of volunteers for use in future *(general/medical/specific disease)* research.

*For specimen banks:*If you agree to participate, we will securely store your samples *(specify type, e.g., blood, tissue)* along with some basic information *(specify if applicable: race, diagnosis, ethnic group, geographic region, sex, and age range).* We will keep the samples forever or until used up.

*For data registries:*

If you agree to participate, we will securely store your *(specify: medical record information; clinical results, diagnosis and treatment information; information about your condition/disease; etc.)* for future research.

Researchers can request to use the stored *samples/information* for their studies on *(specify type of research or indicate if may be on any research topic)*. *(Include if applicable)* The bank/registry will remove all information that could identify you before sharing with researchers.

Researchers may do laboratory, animal, or genetic studies with your sample. Genetic studies identify a role genes play in health, disease, traits, behavior, and ancestry. See the Detailed Consent for specifics.

Researchers may place results from their studies in scientific databases, which combine information from large numbers of people. This allows scientist to see trends and do studies that are more powerful. The results will not include your name or information that could identify you. See the Detailed Consent for Privacy Protections.

**What are reasons you might choose to volunteer for this *BANK/REGISTRY*?**

Participating is not likely to benefit you personally, medically, or financially. Some volunteers get satisfaction from contributing to research that may help others in the future. The *bank/registry* will take careful steps to keep your information confidential. In addition, there are laws that make it illegal to discriminate against you based on your genetic information.

**What are reasons you might choose NOT to volunteer for this *BANK/REGISTRY*?**

In spite of the security methods we use to protect your information, we cannot guarantee that your identity will never become known. We do not know whether advancing technology will increase this risk in the future. *Include if applicable:* Genetic information is unique to you. The Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress. Generally, tests done for research purposes are not meant to provide clinical information. We do not plan to provide you with individual results from the *(research/genetic tests).*

**DO YOU HAVE TO TAKE PART IN THE *BANK/REGISTRY*?**

If you decide to take part, 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.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

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

**detailed consent***Remove instructions & text that does not apply!*

**WHAT WILL HAPPEN IF YOU JOIN THE *BANK/REGISTRY*?**

Having *information/samples* from many people allows the researchers to 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.

*For banks:*

The bank provides a ready supply of samples, so researchers do not have to look for donors for each new study.

*(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. We may mix your cells with other human cells or implant them in laboratory animals such as mice.

*(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.   
*(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 IS THE *BANK/REGISTRY* LOCATED?**

The bank/registry is located at *\_*\_\_\_\_\_\_\_\_\_\_\_ *(describe location/facility).*

**WHAT WILL BE STORED IN THE *BANK/REGISTRY*?**

***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. There is usually leftover sample that the lab discards unless you permit us to use it for research purposes. 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 samples:***

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.

***Specify frequency if investigator will contact participant 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. The confidentiality section below provides details about how we will keep your information private.

**HOW WILL THE *BANK/REGISTRY* USE AND SHARE YOUR *SAMPLES/INFORMATION* WITH OTHER RESEARCHERS?**

The bank will use your identifiable specimen and information for future research.

The bank will share your specimen and information with other researchers for future research.

***If plan includes sharing de-identified information:***

We will remove all information that could identify you before sharing your *information/sample* with other researchers. *Include if applicable:* We will use \_\_\_\_\_\_\_\_ (*a process, software, barcodes*) to track information shared without releasing your identity. (The researchers who receive your *information/sample* will sign an agreement promising to use responsibly.

***If identifiable information or specimens will be shared (e.g., medical record number; fresh tissue with collection date):***

If a researcher requests your information or samples with identifiable information, he/she must first have the research reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. The IRB will decide if the research may be conducted with or without your additional consent.

***Add the following to research conducted in the UK healthcare enterprise (EPIC medical records):***Information or results from tests done for this study could end up in your medical record.   That information could be included when in the future, researchers pull big data from the records to answer new research questions.  Researchers from UK may share the big data with other research organizations or businesses without obtaining additional consent from you. However, researchers sharing big data will protect the confidentiality of your information as much as possible.

**Will you be contacted about participation in future studies?**

***Specify future contact:***

Neither the *bank/registry* nor researchers who access *samples/information* from the *bank/registry* 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>.

*OR*

The *Bank/Registry* would like to contact you with information about participating in future studies, If so, it will be limited to *(specify frequency)* times per year.

## Do you give your permission to be contacted in the future regarding your willingness to participate in future research studies?  Yes  No Initials\_\_\_\_\_\_\_\_\_

**ARE THERE RISKS FROM PARTICIPATING IN THE *BANK/REGISTRY*?**

***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 collecting additional blood 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 collecting additional tissue 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 stored information or specimens. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known. You can reduce the risk by not sharing information about taking part in the *registry/bank*.

***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 to someone to trace your genetic information back to you.

**HOW IS YOUR PRIVACY AND CONFIDENTIALITY PROTECTED?**

*Describe procedures for protecting confidentiality of stored information/samples (e.g., encrypted electronic files, code lists, secure code keys, de-identification measures and/ or honest broker procedures). Indicate who will have access to identifiable or coded information.*

The bank/registry will take careful steps to keep your information confidential. We will remove your name and other direct identifiers from your *information/sample*. We will label your information with a code. Only the *bank/registry* staff will have access to the master list that links the code to you.

We will make every effort to safeguard your information/samples. We will store the coded *information/samples* in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*describe security of storage, e.g., secured computer/server; REDCap, locked freezer*). *Add the following information if REDCap is being used for storage of identifiable data:* REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will protect the information with passwords/encryption. Encryption changes your information to another format to protect it from being accessed by anyone outside of the approved staff.

The researchers requesting access to *information/samples* from the bank must (*specify*, *complete an application process; sign an agreement; or be approved by an oversight committee).* *Indicate what is required in order to provide data to recipient researchers (e.g., an application, a data-use agreement or oversight committee approval).* We will review the researcher’s qualifications and the proposed research to determine if any additional review or approval is necessary.

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

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 based on already known genetic disease.

The staff follow procedures to protect your identity to the extent allowed by law. In very unusual cases, staff may be required to release your identifiable medical and research information in response to an order from a court of law. 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 that may have access to information)* may look at or copy pertinent portions of records that identify you.

*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 protection 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.

***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.*

**WHAT HAPPENS IF YOU GET SICK DURING SAMPLE COLLECTION?**

*ONLY Include this section for:*

* *greater than minimal risk research;*
* *research involving invasive procedures to collect samples (e.g., biopsy); or,*
* *collection of extra tissue during a clinical procedure.*

*Otherwise, delete this section.*

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, Bank Director’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. *in addition to one or more of the above, as deemed necessary, 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. In addition, 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, for example):*

* 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.).

Your insurer or Medicare/Medicaid may need a copayment/deductible 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.

**Does taking part in the *bank/registry* cost anything?**

There will be no additional costs or charges to you for taking part in the *bank/registry*. 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 *information/sample* 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 or be used for commercial profit. There are no plans to provide financial payment to you or your relatives if this occurs.

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

*Include if NOT sharing individual results.* Generally, tests done for research purposes are not meant to provide clinical information. Since the results are only important for research, the *bank/registry* has no plans to provide you with individual test results. The researchers who access your *samples/information* will not have access to information that identifies you. Therefore, they will not provide you with research results.

*Include if bank/registry will share individual clinically relevant results. Provide conditions for sharing (e.g., results that are actionable, medically relevant and/or clinically confirmed).* 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 bank/registry; a special committee; an expert consultant; the IRB)* to determine if it is in your best interest to contact you.

If so, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*the bank/registry and/or your primary care provider and/or genetic counselor*) will contact you at the contact information you provided. They will present possible advantages and disadvantages of receiving the information. At that time you can choose to receive or refuse the result or finding.

***OR***

Do you give permission for (*the bank, researchers*) to contact you with information about research results or findings that are determined to be important to you/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/registry phone and mailing address)*.

**Are there other choices if you do not want to participate in the *BANK/REGISTRY*?**

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

**WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR *INFORMATION/SAMPLES*?**

You may withdraw your permission to use your *information/ samples* for future research. To do so, you must send a written withdraw request to \_\_\_\_\_\_\_\_\_\_ (*insert address)*.

We will destroy any remaining *information/ samples*. In addition, it may be possible to destroy the code that links you with your information. However, we cannot withdraw the information that has already been shared with other researchers or placed in shared databases.

**WHAT ELSE DO YOU NEED TO KNOW? *(remove if unfunded)***

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

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

*If protected health information (PHI) is used to create the repository, include the following HIPAA Authorization.*

**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 and used to create the *bank/registry* includes:

* (*List all of the protected health information\* to be collected 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)*

If mandated, the bank/registry may be required to 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 (EPIC, the electronic medical records) if applicable. You must include this item if you are providing financial compensation for study participation or obtaining lab results from UKMC.)*
* *(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 your research fall under the purview of a government agency (i.e., FDA, NIH, NIH GDS, etc.) list them in this section of the authorization form.)*
* *(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

Should your protected health information have to be released to an entity listed above that is not regulated by HIPAA, the use of your health information may still be regulated by other applicable federal and state laws.

You may not be allowed to participate in the research *bank/registry* 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/registry* **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/registry* 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 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.**

**INFORMED CONSENT SIGNATURES**

**We will provide you with a copy of this consent form after signing.**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **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:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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