**This is a written consent template for biomedical research studies. This template includes HIPAA authorization but can easily be removed.**

* It must be edited to include study-specific information.
* Remove the italics when study-specific text has been added. The text not italicized should stay in.
* If this will be used for parental or guardian consent of a child, change “you” to “your child” where appropriate.
* Review the separate template document called “Example Consent Text for Study-Specific Activities” to ensure no other text needs to be included.
* Use plain language, generally at an 8th grade reading level. Avoid jargon and complex terms unless defined. Avoid 1st person.
* You must delete all this red text and reformat before submitting to the IRB

**Written Consent to Participate in a Research Study**

**Project Title:** *(insert title)*

**Principal Investigator Name:** *(insert PI name and advisor if this is a student-led project)*

**Sponsor:** *(insert sponsor name if sponsored or remove)*

**IRB Assigned Project Number:** *(insert the IRB project number)*

**Key Information About the Study**

You are being asked to participate in a research study *(if this is a clinical trial, the term must be substituted where necessary in this document)*. The purpose of the research study is *(Provide a brief summary of the purpose of the research. More detail can be included later).* You are being asked to *(describe what they are mainly being asked to do).*  Possible benefits include *(include a brief summary here).* Some possible risks may include *(include a list of the most important potential risk(s) in this section).*

Please read this form carefully and take your time. You can discuss this study with your family, friends, or doctor if you want. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled. *(If there are consequences of a subject’s decision to withdraw from the research, explain here, and include the procedures for orderly termination of participation by the subject. If it’s possible their participation may be terminated by the investigator without regard to their consent, explain here)*

**Purpose of the Research**

You are being asked to participate in this study because *(describe why they were chosen to participate).* The purpose of the study is to *(insert purpose of the study here).*

*(If there any conflicts of interest to disclose, include here otherwise remove).*

*Refer to the “Example Consent Text for Study-Specific Activities” document for relevant text related to specific research tests, procedures, or processes. This would apply for drug and device studies, use of placebos, etc.*

**What will happen during the study?**

If you take part in this study, you will have the following tests and procedures:

*Describe all research activities required of them – include lists, bullets, or other organized ways to present the information.*

*Different visits should be separated with clear expectations for each visit and the location. List any procedures which are experimental – stating whether they are standard of care or research only.*

*If some tests or procedures are optional, this must be clear. Refer to the “Example Consent Text for Study-Specific Activities” document for relevant text related to specific research tests, procedures, or processes. This would apply for randomization, blinding, scans, radiation, MRIs, etc.*

There will be about *(include number of subjects)* participating in this study.

*Only include the following two statements if the study collects biospecimens (i.e. saliva, urine, blood, tissue) – if not, remove both:*

Your biospecimens may be used for commercial profit, but you will not share in this commercial profit. *(If they receive profit, this will need to be edited)*

The research might include whole genome sequencing (i.e. sequencing of a human germline for somatic specimen with the intent to generate the genome or exome sequence of the specimen). *(If this will definitely happen, change “might” to “will”, or remove altogether if it will not happen)*

**Will you share with me any results or health problems/issues that you learn about me while in the study?** *(Include this section for studies involving radiological procedures or utilizing biospecimens, or as applicable to your study)*

*Add the following for non-clinical trials:*

The study investigators are not medical doctors and the *(name of procedure)* is/are being conducted for research purposes only. The results of this procedure might detect or identify a health problem or issue of which you are not aware (or even one of which you are aware). But the primary purpose of this procedure is research, not the detection or identification of health problems or issues you may or may not know about. If the investigators identify potential health problems or issues as part of the research, you will be provided with this information and, with your permission, the investigators will share this information with your primary care physician or other healthcare provider of your choice. It is possible that you may need testing or treatment for a new or existing health condition. You and/or your health plan/insurance are responsible for the costs of this testing or treatment.

*Add the following for clinical trials:*

If we find any clinically relevant research results as a result of *(study-specific tests or procedures)* that include results about you, we will inform you as soon as possible. If the investigators identify potential health problems or issues as part of the research, you will be provided with this information and, with your permission, the investigators will share this information with your primary care physician or other healthcare provider of your choice. It is possible that you may need testing or treatment for a new or existing health condition. You and/or your health plan/insurance are responsible for the costs of this testing or treatment.

**How long will I be in the study?**

Your participation is expected to last *(include expected duration – describe active participation vs. follow up activities).*

**Are there benefits to taking part in the study?**

You may or may not benefit as a result of your participation in the study. Information learned from the study may help other people in the future. *(this is just sample text; it must be edited to describe whether they may expect direct benefits or if there are no direct benefits. Study-specific information must be included here)*

**What are the possible risks of participating in this study?**

There are risks expected when taking part in this study. There are some that we know about and some may not know about yet. Some risks include *(this is just sample text; it must be edited to describe potential risks – list in order or severity and frequency).*

To help lower these possible risks, we will *(describe what is being done to minimize risks to subjects).*

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

*Only include the following statement if applicable – if not, remove:*

If you are pregnant or become pregnant while in this study *(add timeframe if expands beyond study)*, there may be risks to you, the embryo or fetus that we do not know yet. *(Include precautions the study is taking to minimize these risks – i.e. pregnancy testing Refer to the “Example Consent Text for Study-Specific Activities” document for pregnancy risk language.*

What other choices do I have if I don’t want to be in this study?

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study. The research team can share other options that may be available to you. *(list any alternative procedures or courses of treatment, if any, that may be advantageous to the subject, mention if they should also discuss with their doctor).*

Will I receive compensation for taking part in this study?

*Include one of the following statements – remove the other:*

You will not be compensated for taking part in this study.

You will be compensated for taking part in this study. For your time and effort, you will receive *(Include amount, timing, and method of payment/credits. If prorating is necessary, include your proration plan)*

*Only include if SSN is required to collect:*

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

Are there any costs for participating in this study?

*Only include what applies to your study and revise accordingly.*

You should not expect any additional costs by participating in this study. *OR the following statements that apply:*

The study will pay for all research tests and procedures. You and/or your health plan/insurance will not be billed for tests and procedures that are done for research only. *(list the research only tests/procedures)*

*Include the following if the study has standard of care items included as part of the protocol:*

You and/or your health plan/insurance will be billed for everything that is considered standard of care. This includes tests and procedures you would receive without being in this study. Some health plans/insurance companies will not pay for these costs for people who are in research studies. Check with your plan/company to find out what they will pay for.

Other costs to you from being in this study may include testing or treatment for existing or new health conditions, insurance co-payments for doctor visits, transportation, parking, childcare, and/or time off work.

A social worker and financial counselor are available to discuss concerns with you. Please let the research staff know if you would like to visit with them and an appointment will be made.

You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential, including health information. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. *(remove coding language if information will not be coded)*

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed. *(this section will need to be edited as needed)*

*Include for treatment studies where placement of the consent in the medical record is necessary:*

We will scan a copy of this consent form into your medical record. We may also record your research information, including the results of tests and procedures, in your medical record if the information could be useful for future treatment.

*If the project collects identifiable information or biospecimens, you must include one (not both) of the following statements – if no identifiers are collected, then remove all this language:*

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

We may share what we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.

FDA may inspect the records since the study is FDA regulated. *(include only if FDA regulated)*

*HIPAA AUTHORIZATION LANGUAGE: Remove the rest of this text in this section if HIPAA does not apply or subjects will sign a separate HIPAA authorization document. Check with the covered entity where the research will take place to determine if a consent with a combined HIPAA is acceptable.*

Permission to Use your Protected Health Information:

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

*Edit this list to only request minimum necessary information:*

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, fax number, email addresses, medical record number, social security number, account numbers, health plan beneficiary number, certificate or license numbers, vehicle or device serial numbers, web address, IP address, biometric identifiers (finger/voice print), photos, and other characteristics that could identify you.

*If the study involves the collection of sensitive information, include this section:*

Certain sensitive information about you can only be released if you give your specific permission. *Include the sensitive information that will be requested (i.e. mental health information, drug or alcohol use, HIV status, etc.).*

We may share any of this information with the following: *(Delete any that do not apply)*

* Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
* Laboratories and other individuals and organizations that may need to see your health

information in connection with this study.

* Study monitors and auditors who make sure that the study is being done properly.
* *[Insert name of company sponsoring the study]* who is sponsoring the study, and their

contractors and partners.

* Government agencies and public health authorities, such as the Food and Drug

Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

* Others: *[Specify by name or category any other individuals or organizations who may access, receive, or use the personal health information in connection with this research study.]* The following individuals or organizations may also access, receive, or use your personal health information:

Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your permission for us to use and/or release your information will not expire unless you cancel your permission in writing. *If it does expire on a certain date, edit and include here.*

You can cancel your permission at any time by writing to: *[Insert all of this information.]*

Investigator’s Name:

Institution:

Department:

Address:

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

*Include one of these statements about access – remove the other*

You have the right to access your protected health information that is obtained or created during this research project until the end of the study.

You will not be allowed to access your protected health information that is obtained or created during this research project until the end of the study.

*Edit the contact information for the HIPAA covered entity where your research will occur. Only include the first sentence below if the study is being conducted within MU Health Care. Only include the second sentence if your study will be conducted within the MU Health covered entity:*

If you have not already received a copy of the University of Missouri Health Care Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at 573-882-9054.

What if I am injured during the study? *(Remove this entire section if the study is minimal risk. If industry sponsored, you must use the sponsor’s injury language instead of the language below)*

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury.

The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

Where can I get more information about this clinical trial? *(remove entire section if this is not registered on clincialtrials.gov)*

A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher at (*insert phone number and email address*).

If you have questions about your rights as a research participant, or have problems or complaints, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email muresearchrpa@missouri.edu.

**Do I get a copy of this consent?**

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

**Consent to Participate - Signatures**

**Optional Items** *(if the study does not include optional tests/procedures/decisions, remove all options)*

My initials state my choice about the optional tests/procedures/decisions in this study:

I agree to the optional *(include options here – can combine or separate as necessary)*

Yes \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

My initials state my choice about allowing my information/biospecimens to be stored and used for future research:

Yes\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Subject’s Signature** | **Date**  |

*Remove additional signature lines if not required for your study:*

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| **Child’s Name** |

*(Include for Parental/Guardian Consent to help link with child)*

*(If study requires two parent consent, must include an extra subject signature line and date)*

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| **Legally Authorized Representative (LAR)** | **Date**  |

*(Include when adult subject is incapable of providing legal consent)*

***MO Rev Stat 431.064:******Experimental treatment, tests, and drugs, consent to administer by third party — life-threatening emergencies, consent by whom. —***

*1. When an adult person, because of a medical condition, is treated by a teaching hospital for a medical school accredited by the American Osteopathic Association or the American Medical Association and such person is incapable of giving informed consent for an experimental treatment, test or drug, then such treatment, test or drug may proceed upon obtaining consent of a legal guardian, attorney-in-fact, or a family member in the following order of priority:*

*(1) Spouse unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;*

*(2) Adult child;*

*(3) Parent;*

*(4) Brother or sister;*

*(5) Relative by blood or marriage.*

*2. Nothing in this section shall authorize such legal guardian, attorney-in-fact, or family member to consent to treatment in contravention to such incapacitated person's expressed permission regarding such treatment.*

 (L. 1993 H.B. 564 § 33, A.L. 2003 S.B. 431, A.L. 2006 H.B. 1601 merged with S.B. 765)

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| **Relationship to Subject** |

*(Include for LAR and parental/guardian consent)*

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| **Independent Witness** | **Date**  |

*(Required when Subject or LAR cannot read or sign name, and as required by the IRB)*

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| **Investigator Authorized to Obtain Consent** | **Date**  |

*(Required for FDA regulated, and/or treatment/medical procedure studies)*