Sample Adult Consent Template with HIPAA Language– Exempt Studies

* Do not use this template if HIPAA does not apply.
* Insert study-specific language where italics are included below – do not leave it as italics.
* Remove this red text before submitting to the IRB
* Edit as necessary and change blue text back to black
* If used as a parental consent, the “you” should also include “you and your child” or “your child”

**Consent to Participate in a Research Study**

Project Title: *insert title*

Principal Investigator/Researcher: *may also include advisor for student-led projects*

IRB Reference Number: *insert IRB number*

You are being invited to take part in a research project*.* You must be 18 years of age or older. Your participation is voluntary, and you may stop being in this study at any time. The purpose of this research project is (*describe your project*). You are being asked to (*describe what the subject is being asked to do).* Your participation should last up to (*include timeframe*). For your time and effort, we will be offering compensation in the amount of (*include amount and also include payment type. If extra or course credit, include that information with alternative assignment – remove sentence if there is no compensation*). The information you provide will be kept confidential and only the research team will have access (*this sentence may need to be modified depending on whether identifiers are collected and whether identifiers are shared outside the research team).*

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: The following individuals or organizations may also access, receive, or use your personal health information: *[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.]*

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.

If you have questions about this study, 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, 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.

You can ask the researcher to provide you with a copy of this consent for your records, or you can save a copy of this consent if it has already been provided to you. We appreciate your consideration to participate in this study.

*Remove signature lines if you completed a subform in the application for a HIPAA alteration (no signature):*

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

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

|  |
| --- |
|  |
| **Child’s Name** |

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

|  |  |
| --- | --- |
|  |  |
| **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)*