**Example Consent Text for Study-Specific Activities**

This document provides example text that can be used for specific research tests, procedures, or processes. Replace all red text with appropriate wording related to your study. Guidance has been given regarding most appropriate section of the consent to include the text.

Click on the following item(s) below to view text that has been approved by the IRB and may be included in your consent document:

1. [Phase I Drug Studies](#PhaseIDrugStudies)
2. [Phase II Drug Studies](#PhaseIIDrugStudies)
3. [Phase III Drug Studies](#PhaseIIIdrugstudies)
4. [Phase IV Drug Studies](#PhaseIVdrugstudies)
5. [Investigational Medical Device Studies](#invdevice)
6. [GINA Language for Genetic Testing](#GINA)
7. [Placebo](#placebo)
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**Phase I Drug Studies**

Section: Purpose of the Research -

In this study, we want to find out more about the side effects (problems or symptoms) of a drug for *condition*, called \_\_\_\_\_\_\_ (also called the study drug in this form), and what doses are safe for people to take. Everyone in the study will take s*tudy drug*, which is experimental (being tested) and has not been approved by the U.S. Food and Drug Administration (FDA).

We do not know all of the ways *study drug* can affect people. ***If applicable:*** This study will likely not help you or your *condition/symptoms*. We hope the information we get from the study will help us develop a better treatment for *condition* in the future.

Section: Are there benefits to taking part in the study –

This study is not likely to help you, but it will help us to learn more about *procedure/drug/device/intervention*. We hope this information will help us develop new treatments for *condition* in the future.

**Phase II Drug Studies**

Section: Purpose of the Research -

In this study, we want to find out more about a drug, called \_\_\_\_\_\_\_ (also called the study drug in this form), for people with *condition*. We want to find out if *study drug* *reduces the symptoms/other reason* of *condition*, and if it causes any problems (also called side effects).

*Study drug* is experimental (being tested) and *is not yet approved by the U.S. Food and Drug Administration (FDA) / is approved by the U.S. Food and Drug Administration (FDA)* *for use but not in patients with condition being studied/but not when given by \_\_\_\_\_\_\_.*

We are testing *study drug* to see what effect it has on patients with *condition*. We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information we learn from this study will help us to develop a better treatment for *condition* in the future.

Section: Are there benefits to taking part in the study –

We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope that this study will help us to learn more about *procedure/drug/device/intervention*, and to develop new treatments for *condition* in the future.

**Phase III Drug Studies**

Section: Purpose of the Research -

In this study, we want to find out if a drug for *condition*, called \_\_\_\_\_\_\_ (also called the study drug in this form), works better than *comparator/placebo*, *a routine treatment for* *condition/something that looks like the study drug but contains no active medicine.* To do this, we will compare *the two drugs/the study drug and the placebo* in people with *condition* and see which one is more effective at *treating*/*reducing the symptoms/other reasons*.

S*tudy drug* is experimental (being tested) and *is not yet approved by the U.S. Food and Drug Administration (FDA) / is approved by the U.S. Food and Drug Administration (FDA) for use but not in patients with condition being studied/but not when given by\_\_\_\_\_.* S*tudy drug* may work better or have fewer side effects than *comparator/placebo*, but we won’t know until we do more research studies.

We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information we get from this study will help us to develop better treatment for *condition* in the future.

Section: Are there benefits to taking part in the study -

We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope that this study will help us to learn more about *procedure/drug/device/intervention*, and to develop new treatments for *condition* in the future.

**Phase IV Drug Studies**

Section: Purpose of the Research -

The U.S. Food and Drug Administration (FDA) has approved *study drug*, and in this study we want to learn more about \_\_\_\_\_\_\_\_\_\_\_\_\_.

**Investigational Medical Device Studies**

Section: Purpose of the Research -

In this study, we want to find out more about a medical device, called \_\_\_\_\_\_\_ (also called the study device in this form), for people with *condition*. We want to find out if *study device* *reduces the symptoms/other reason* of *condition*, and if it causes any problems (also called side effects).

*Study device* is experimental (being tested) and *is not yet approved by the U.S. Food and Drug Administration (FDA) / is approved by the U.S. Food and Drug Administration (FDA) for use but not in patients with condition being studied.*

We are testing *study device* to see what effect it has on patients with *condition*. We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information we learn from this study will help us to develop a better treatment for *condition* in the future.

**GINA Language for Genetic Testing**

Section: Will information about me be kept private –

*Include one of the following two paragraphs:*

We will be doing genetic testing in this study. We will test your *blood/saliva/tissue/other* for *types of tests.* You and your personal doctor will receive the results of the genetic tests. A genetic counselor will be available to *discuss/give you* the results.

***OR***

This study includes genetic research. We will not use the results of this research in your medical care. You and your personal doctor will not receive the results of this research.

*Include this paragraph:*

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

• Health insurance companies and group health plans cannot request your genetic information that we get from this research.

• Health insurance companies and group health plans cannot use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees cannot use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

**Placebo**

Section: Purpose of the Research -

To find out if *study drug/device/intervention* works better than *comparator* for *condition*, this study has *[#]*groups. One group will take *study drug*, and the other group will take *comparator/placebo* ***[add groups as applicable].******[If study includes a placebo]:***A placebo is a *pill/tablet/medicine/infusion/other* that looks like *[study drug & comparator]* but does not contain any real medicine. We will check the symptoms of everyone in the groups in XX *months/weeks* and every \_\_\_\_\_\_\_, and compare the results.

Section: What are the possible risks of participating in this study -

If you are in the placebo group, you will go without drug treatment for your condition for \_\_\_\_\_ weeks/months.

**Randomization**

Section: What will happen during the study -

Because we don’t know which of the *drugs/devices/interventions* is best, we will “randomize” you into one of the *[#]* study groups. “Randomize” means putting you into a group by chance. It is like flipping a coin or pulling a number from a hat. You will have a(n) *equal/one in three/etc.* chance of being placed in *either/any* group. A computer program chooses which group you go in. You *and the study doctor* ***[if applicable]***cannot choose which group you go into.

Section: What are the possible risks of participating in this study -

You will be put into a group by chance. The *drug/device/intervention* you receive may turn out to be less effective or have more side effects than that in the other groups. It may also be less effective and have more side effects than other *drugs/devices/interventions* available for *condition.*

**Blinding**

Section: What will happen during the study -

***Adapt for single or double blinded:***This study is “blinded”, which means that you *and the study team* ***[if applicable]*** will not know which *drug/device/intervention* you are getting until the end of the study. This way, no one’s expectations of what will happen in the study will affect the results.

In an emergency, the study doctor can find out which *drug/device/intervention* you are getting.

Section: What are the possible risks of participating in this study -

***For blinded studies, add:***While you are in this study, we will not know which *drug/device/intervention* you are getting. If your condition gets worse during the study and we need to know which *drug/device/intervention* you are getting*,* there will be a way for us to find out.

**CT Scan**

Section: What will happen during the study -

You will have a computed tomography (CT)/computerized axial tomography (CAT) scan of your *body part* ***describe when/how often*.** A CT/CAT scan uses special x-ray equipment to make detailed pictures of body tissues and organs.

For the scan, you will lie still on a table with your *body part* inside a large doughnut-shaped machine. The table will move and the machine will make clicking and whirring noises as it takes the pictures. ***If appropriate:*** Before the scan, you will have an iodine dye *injected into your vein/given to you by mouth/by rectum.* The dye makes it easier to see tissues and organs in the pictures. Each scan takes about \_\_\_\_\_\_ minutes.

Section: What are the possible risks of participating in this study -

CT and CAT scans have radiation risks just like x-rays. The scanner may make you feel uncomfortable if you don’t being in small spaces or having to lie in one position for a long time.

***If a contrast dye will be used:*** Sometimes, a contrast fluid (iodine dye) is used for a CT scan so that the inside of your body shows up better in the pictures. There is a slight risk of an allergic reaction from this dye. The reaction can be anything from mild (itching, rash) to severe (difficulty breathing, shock, or rarely, death). It may also cause kidney problems if you are dehydrated or your kidneys do not work well. The study doctor will ask you about any allergies you have. If you have any of these problems, you will not be allowed to *have a CT scan/stay in the study.*

You may feel uncomfortable when the contrast dye is *injected/given by* \_\_\_\_\_\_. It sometimes causes a warm, flushed feeling, or a metallic taste in the mouth. In rare cases, it can cause nausea, vomiting, or a headache.

**Radiation**

Section: What will happen during the study -

This example is for x-rays but can be adapted:

You will have an x-ray of your *body part* taken ***describe frequency/ when****.* Each x-ray will take about \_\_\_\_\_ minutes.

Section: What are the possible risks of participating in this study -

The amount of radiation you will be exposed to is quite small, but could possibly be harmful. Radiation effects build up over time. You should always let other doctors know that you had x-rays as part of this study.

### The radiation you will receive is the same as you would have if you were not on the study.

### ***OR***

### The radiation you will receive will be about as much as most people are exposed to from background radiation *every day/over \_\_\_\_ days/months/years*.

If you have already had a lot of x-rays or are worried about radiation risks, please discuss this with the study doctor before you agree to be in this study.

**MRI – Magnetic Resonance Imaging**

Section: What will happen during the study -

You will have a Magnetic Resonance Imaging (MRI) scan of your *body part* ***describe when/how often***. The MRI scanner takes pictures of the inside of your body using a very strong magnet.

For the MRI, you will lay on a table that will slide into the middle of the magnet. You will have to lie still while the MRI is working. The MRI takes about \_\_\_\_ minutes.

Section: What are the possible risks of participating in this study -

The magnet in the MRI machine is very powerful and attracts any metal objects brought into the room. People with heart pacemakers or other metal objects in their body cannot be in the study because they cannot go in the MRI room.

The MRI scan is painless but it can be uncomfortable for some people. The machine makes lots of loud beeping and hammering noises that can bother some people e. You will wear earplugs or headphones during the scan to protect your ears. You may also feel something like a mild electric shock or gentle tapping on your body during the scan. This is normal and happens when the nerves in your body are stimulated by the magnets.

The MRI scan may bother you if you feel uncomfortable in small spaces. You will be able to speak to us through an intercom during the scan, so you can ask us to stop the test at any time.

**Incidental Findings**

Section: 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.

**Mandated Reporting**

Section: Will information about me be kept private -

Edit as needed depending on population studied and type of information collected:

We *will/might* collect information from you that indicate the possibility of child abuse or neglect/elder abuse or neglect/intent to harm yourself or others/sexual harassment/sexual violence. One or more of the study staff are mandated reporters. This means that they are required by law to report any of these findings to the appropriate state agencies. These agencies include ***(the select the applicable agency)*** *the Missouri Department of Social Services/Missouri Department of Health and Senior Services/Title XI officials/other.*

**Audio/Video/Photographs**

Section: Will information about me be kept private -

You must give us permission to publish the *images/photographs/audio recordings/video recordings* we take of you during the study. *If applicable:* You will be able *look at/listen to/watch* them before you give your permission for us to use them.

*Include if will be de-identified: Images/photographs/audio recordings/video recordings* will not contain anything that might identify you.

**Certificates of Confidentiality**

Section: Will information about me be kept private -

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

**[*You may use the following language as applicable*]** The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [*University of Missouri or sponsor*] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

**[*Include this statement if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws*.]** The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [*list what will be reported, such as child abuse and neglect, or harm to self or others*].

**[*Include this statement* *if researcher intends to disclose information covered by a Certificate, with the consent of research participants*.]** The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [*restate what will be disclosed, such as including research data in the medical record*].

**Pregnancy Risks**

Section: What are the possible risks of participating in this study -

Pregnancy Tests: The *drug/procedures/intervention* used in this study may affect unborn babies. For this reason, pregnant women cannot take part in this study. If you are a female who can become pregnant (you have had your first period and have not reached menopause), we will do a *urine/blood* pregnancy test to make sure you are not pregnant.

* Risks to women who could become pregnant:

The *drug/intervention* in this study might affect a baby, before or after it is born. We do not know if the *drug/intervention* can harm a baby, and so we do not want anyone who might be pregnant to be in the study.

You should not become pregnant or breastfeed a baby while taking part in this study and for \_\_\_\_ *weeks/months* after \_\_\_\_\_\_\_. You must use effective birth control while you are in the study and for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ after \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

You must tell the study doctor right away if you think you are pregnant. We will ask you to take a pregnancy test to be sure you are not pregnant *at the start of the study/during the study/at the end of the study.*

* Risks of fathering a child: *Include this only if there is evidence or concern that the drug causes paternity-related birth defects, or if required by sponsor.*

You should not *father a child/get your partner pregnant* while you are in this study and for \_\_\_\_\_\_ after \_\_\_\_\_\_\_\_\_. If your partner is able to get pregnant, one or both of you must use effective birth control. You must tell the study doctor right away, if you think your partner is pregnant while you are in the study.

* Acceptable birth control male and female participants:

If you are having sex that could lead to pregnancy, you should use one of the birth control methods in this list: *Select all or those that apply to your study*

* Not having vaginal sex (abstinence)
* Taking birth control pills by mouth
* Having birth control shots or patches, such as Depo-Provera
* Surgical sterilization (tubal ligation [tubes tied] or hysterectomy)
* Using an intrauterine device (IUD)
* Using a diaphragm with contraceptive jelly
* Using condoms with contraceptive foam
* Using a diaphragm with condoms (double barrier)
* Only having sex with a man who has had a vasectomy

You should continue using birth control for *\_\_\_ months/weeks* after stopping \_\_\_\_\_\_\_.

**HIPAA Authorization**

Section: Will information about me be kept private -

*HIPAA AUTHORIZATION LANGUAGE: 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 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 study ends.

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.

**MU Injury Language**

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.