University of Colorado Denver

Note: This document contains only the consent form requirements for the institution. It is not a complete template.

Check the submitted consent form, protocol level WIRB approved consent form template, or the sponsor’s template for the sections that need additional language. If the language is not in those documents, contact the site for the information.

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Use WIRB standard headings – plus add the institution tracking number.

**Protocol No.:**

WIRB® Protocol #

IRB ##-####

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**Who is sponsoring this study?**

The site will submit the language below. Deviations from this text are acceptable:

This research is being paid for by [sponsor name], the manufacturer of the study [drug/device].

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Will I be paid for being in this study?

The site must choose statement that applies, deviations from this text are acceptable. This institution requires that a statement that a subject will not be paid be in the consent form:

You will be paid [$XX.XX] for each study visit that you complete. [if the amount will vary from visit to visit, state the different amounts and visit types]. This will add up to a total of $XXX.XX if you complete all of the study visits [if some subjects may get a particular procedure while others may not, break this into different amounts and explain]. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

Payment for participation in a study is taxable income.

OR

You will not be paid to be in the study.

OR

If Children’s Hospital is Paying for Participation the site will add:

You can be paid for being in this study. Children’s Hospital Colorado pays you using a debit card system. The cash value will be loaded onto a debit card when you finish certain study procedures. The Internal Revenue Service (IRS) requires that we report as income when we pay you. A research team member will ask you to provide your social security number or tax identification number to meet these IRS requirements. Without this number, we can’t pay you for being in this study.

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Will I have to pay for anything?

The site must choose statement that applies:

You will need to pay for . . .

OR

You will not be charged for the study drug/device or any of the study procedures or office visits.

For oncology studies only:

The study sponsor, [sponsor name], will pay for the cost of the study drug.

The sponsor will also pay for any tests or procedures that are related to the research study.

You will need to pay for any tests and procedures that are considered standard of care. These include the CT scans, MRI’s and some clinic visits and laboratory tests. You may be responsible for co-payments and deductibles that are standard for your insurance coverage.

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

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**What happens if I am injured or hurt during the study?**

Plans for injury and compensation must be included for research involving more than minimal risk**, do not include if the study is minimal risk.**

**PLEASE NOTE:**  The wording that is submitted in the consent form should remain AS IS if accompanied by an approval email from University of Colorado Denver.

Add the following text as the first paragraph of the section:

If you have an injury while you are in this study, you should call [insert name] immediately. [His/her] phone number is [insert phone number].

**Option 1:**

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

OR

**Option 2:**

If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the investigator will determine if your injury or illness is research-related. The term “research-related injury” means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.

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**Who do I call if I have questions?**

Add the submitted, sponsor’s, or WIRB approved text – plus the following after WIRB’s contact information:

OR

Colorado Multiple Institutional Review Board (COMIRB) office at 303-724-1055

WIRB is a group of people who perform independent review of research under contract with the University of Colorado Denver.

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Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: [delete those that do not apply for this study]

* University of Colorado Denver
* University of Colorado Hospital
* Children’s Hospital Colorado (Children’s Colorado)
* Denver Health
* National Jewish Health
* Other [name; use this space for other **affiliated** institutions only, such as Barbara Davis Center, etc.]

If the study is being conducted at Children’s Colorado add the following paragraph:

Children’s Colorado shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that other healthcare professionals could view your information.

We cannot do this study without your permission to see, use and give out your information.  You do not have to give us this permission.  If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit.  You can cancel your permission to use and disclose your information at any time by writing to the study’s Principal Investigator (PI), at the name and address listed below.  If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected.  Your cancellation would not affect information already collected in this study.

  Enter PI Name and Mailing Address

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

* Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
* People at the Colorado Multiple Institutional Review Board (COMIRB)
* *[if applicable, if COMIRB is not the IRB of record]* The Institutional Review Board that is responsible for overseeing this research
* The study doctor and the rest of the study team.
* *<insert sponsor name>,* who is the company paying for this research study, and its agents who perform services in conjunction with the study.
* Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
* *<add any other groups or entities that are applicable; this section is only for entities that have the legal right to audit study records>*

We might talk about this research study at meetings.  We might also print the results of this research study in relevant journals.  But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed – if applicable].

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make all or some of the following health information about you collected in this study available to: *(This section is for outside disclosures of research information that you will make. Name of specific study-related person or group, external to UCD, such as the Sponsor, specific lab or Contract Research Organization (CRO). Include recipients of information for optional research procedures. If no outside disclosures of data, delete)*

* The other organizations involved in this study, including *<add any other Sites involved in the research study >*, and any others involved in this study who have a need for your information to accomplish the study objectives.
* *<Data Coordinating Center>,* who coordinates the data for this research study, and its agents who perform services in conjunction with the Study.

If applicable: Some of the research procedures involve genetic testing or the use of your genetic information. Your genetic information [choose one] will not be released to others or will be released to:

**Information about you that will be seen, collected, used and disclosed in this study:**

The site will delete all that do not apply

* Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
* Your social security number
* Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
* Research Visit and Research Test records
* Psychological tests
* Alcoholism, Alcohol or Drug abuse
* Testing for or infection with diseases reportable to the Public Health department, including but not limited to: Human Immunodeficiency Virus (HIV), hepatitis (all forms) tuberculosis, or other sexually transmitted diseases.
* Testing for sickle cell
* Tissue samples and the data with the samples.
* Billing or financial information
* Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**What happens to Data, Tissue, Blood and Specimens that are collected in this study?**

The site will delete the types of data that do not apply, in heading and in the following text

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

* The data, or the tissue, blood, or other specimens are given by you to the investigators for this research and so no longer belong to you.
* Both the investigators and any sponsor of this research may study your data and tissue, blood, or other specimens collected from you.
* If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
* Any product or idea created by the researchers working on this study will not belong to you.
* There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

The University of Colorado Denver has standardized language for tissue banking or storage of samples for future use which can be found on the COMIRB website.

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**HIPAA Authorization for Optional Additional Study Procedures** – [if applicable]

If there are no optional procedures in this study or the optional procedures are in the addendum consent form, delete the HIPAA Authorization for Optional Additional Study Procedures below

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

[if applicable] Some of these optional procedures may involve genetic testing or the use of your genetic information. Your genetic information [choose one] will not be released to you or others or will be released to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

\_\_\_\_\_ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

\_\_\_\_\_ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

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Agreement to be in this study:

For Children’s Hospital submissions, please see the Children’s Hospital signature line template.