Principal Investigator:

Phone or email:

COMIRB No:

Version Date:

Study Title:

[*Delete instructions in italics from the final consent form. Use plain language throughout the consent form. Resources for recommended wording for a variety of procedures, risks, and other topics for consent forms, can be found on the COMIRB website.*]

[*For research that includes Children's Hospital Colorado as a performance site, please see additional required CHCO language by clicking* [*HERE*](https://research.cuanschutz.edu/comirb/home/children's-hospital-colorado)*.*]

You are being asked to be in a research study. Participation is voluntary. This form describes the study. A member of the research team will explain the study to you and answer all of your questions. Take your time to read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

**Why is this study being done?**

We are doing this study to learn more about .... You are being asked to be in this research study because [you are ..., or you have ...].

To do this research, we are asking for tissue samples (such as blood, urine, saliva, etc.) and health information from patients like you. We will use the tissue samples and health information for research now and in the future.

**What happens if I join this study?**

*[Describe study procedures chronologically. Explain where study visits take place, how long they will last, and how many visits are required. Also, indicate how long overall study participation will last. Edit statements below as appropriate for your study. Delete statements that do not apply.*]

We will collect blood samples from you at [describe time points]. The blood samples will be taken from an existing IV line or when other blood samples are being drawn as part of your routine health care. Each sample will be about [amount] tablespoons. A total of about [amount] tablespoons will be taken for the whole study. No additional needle sticks will be performed for research purposes.

We will collect blood samples from you at [describe time points]. The blood samples will be taken by inserting a needle into a vein in your body and letting the blood flow into a glass tube. Each sample will be about [amount] tablespoons. A total of about [amount] tablespoons will be taken for the whole study.

We will collect a sample from your nose with a nasal swab at [time points]. The swab will be gently inserted into the nasal passage up to the nasal bridge and brushed against the mucous membranes.

We will collect information from your medical records. This will include information related to your diagnosis and treatment, such as previous test results, prescriptions, and images from medical scans you have undergone.

We will ask you to complete questionnaires about your health and medical history.

**What are the possible discomforts or risks?**

[*Describe all reasonably foreseeable risks related to study procedures and/or participation.* *Edit statements below as appropriate. Delete statements that do not apply.*]

When we take blood samples, you may feel some pain when the needle goes into your vein. Drawing blood may also cause bruising, infection and fainting.

The nasal swabs may cause slight discomfort.

If you join the study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential, but we cannot guarantee total privacy.

**What are the possible benefits of the study?**

We hope to learn new information that will benefit society and patients like you in the future. However, the immediate aims of this research will not directly benefit you. We will not provide any research test results to you or your medical provider.

**How will my samples and information be used?**

[*Delete statements that do not apply. If you delete the paragraphs about genetic research and GINA, the samples collected may not be used for genetic research in the future without additional consent. If you delete the paragraph about cell products, the samples collected may not be used to create cell products in the future without additional consent.*]

The samples and information collected for this study will be studied for the purposes described above. We intend to publish and share the results of this study. Your identity will be kept private when we publish and share our results. We will use and store your samples and information as long as they are useful, until you decide to stop participating, or until we close the study.

We may share study data in public or restricted data banks so that the data may be used by other researchers. Your name and other information that could directly identify you will not be sent to data banks without your permission. Even though information that directly identifies you will not be shared, we cannot guarantee that no one will ever be able to use this information to identify you. Broadly sharing data in this way may involve risks to you or others that are unknown at this time.

Study samples and data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed. Future research could be about your condition or other related medical conditions. Other researchers may work for other universities, the government, or private industry.

Future research could lead to the creation of a self-renewing cell line. Cell lines could be shared, patented or licensed for scientific or medical uses. If any new discoveries from this research have potential commercial value, you will not share in any financial benefits.

Future research may include genetic research on your DNA. Researchers study DNA to learn about genetic factors that contribute to health and disease. This [will, might, or will not] include sequencing your entire genome.

Genetic Information Nondiscrimination Act (GINA)

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 generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not 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.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

We may contact you in the future to ask you to participate in additional research. You are free to say no to any future requests.

**Who is paying for this study?**

Support for this research is provided by [name of sponsor, or the university if unfunded].

**Will I be paid for being in the study?**

[*If participants will be paid, explain how they will be paid (e.g., debit card, check at Denver Health), the payment schedule, and how payments will be prorated if the participant does not complete the entire study. Edit statements below as appropriate. Delete statements that do not apply.*]

You will not be paid to be in the study.

You will be paid [$] for each visit in this study. This will add up to a total of [$] if you complete all of the visits. 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.

You will receive these payments by debit card. The Internal Revenue Service (IRS) requires that we report what we pay you as income. A research team member will ask you to provide your social security number or taxpayer identification number to meet these IRS requirements. Without this number, we can’t pay you for being in this study.

**Will I have to pay for anything?**

It will not cost you anything to participate in the study.

**Is my participation voluntary?**

Joining the study is voluntary. If you choose to take part, you have the right to withdraw your permission at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you withdraw your permission, your identifiable samples and information will no longer be used. However, it will not be possible to delete data that has already been generated from the research. If you decide to withdraw, please contact study staff by email at [email], by phone at [phone], or by mail at [address].

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

[*If the research poses minimal risk, delete this section.*]

If you have an injury while you are in this study, you should call [insert name] immediately. [His/her] phone number is [phone number]. In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

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

The researcher conducting this study is [investigator name]. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call [investigator name] at [investigator phone number].

You may have questions about your rights as someone in this study. You can call [investigator name] with questions. You can also contact the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055 or email them at COMIRB@ucdenver.edu.

**Who will see my research information?**

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems 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; these bullets should list only local institutions.*]

* University of Colorado Denver | Anschutz Medical Campus
* University of Colorado Health (UCHealth)
* Children’s Hospital Colorado (CHCO)
* Denver Health and Hospital Authority
* Veterans Health Administration (VHA)
* Other (name; use this space for other affiliated institutions only, such as Barbara Davis Center, etc.)

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 our Notice of Privacy Practices; however, people outside the University 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 any information already collected in this study.

[PI Name]

[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.
* 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.
* 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.]

You have the right to request access to your personal health information from the Investigator.

[*The following section is for outside disclosures of research information that you will make. Include the name of the specific study-related person or group, external to the University, 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 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:**

* [Sponsor]
* [CRO]

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

[*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 and mental health 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 information with the samples.
* Billing or financial information
* Other: [specify]

**What happens to Samples and Information that are collected in this study?**

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The samples and information collected from you during this study are important to this study and future research. If you join this study:

* The samples and information given by you to the investigators for this research no longer belong to you.
* Both the investigators and any sponsor of this research may study your samples and information collected from you.
* If the samples and information are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (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.

**Agreement to be in this study and use my samples and information**

I have read this paper about the study, or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study. I will get a signed and dated copy of this consent form.

Signature of participant Date

Printed name of participant

[*If you are seeking COMIRB approval to enroll minors, include parental signature lines below and ask minors aged 13-17 to indicate their assent by signing above. A separate assent form should be used for minors aged 7-12. If the study will only enroll adults, delete parental signature lines.*]

Signature of parent or guardian Date

Printed name of parent or guardian

Signature of person obtaining consent Date

Printed name of person obtaining consent

[*If you are seeking COMIRB approval to obtain consent from Legally Authorized Representatives, include the signature lines below. Otherwise, delete these signature lines. (Note: Proxy Decision Makers may not provide consent for research involving no prospect of benefit to the participant.)*]

Signature of Legally Authorized Representative Date

Printed name of Legally Authorized Representative

[*Include the following if you may enroll participants who do not speak English using a short form consent process, and if you may enroll participants who are blind or illiterate. Otherwise, delete these signature lines.*]

Signature of witness to the consent process Date

(Only necessary for enrollment of participants who do not speak English when a short form consent process is used, or for enrollment of participants who are blind or illiterate.)

Printed name of witness