Study Title:

Principal Investigator:

IRB ID:

What is this document?

This is a HIPAA Authorization form. It will describe how your health information will be used for this study and by whom. Signing this form indicates you are willing to allow your health information to be used for this study.

What should I do next?

1. Read this form, or have it read to you.

2. Make sure the study doctor or study staff explains the form to you.

3. Ask questions (such as time commitment, unfamiliar words, etc.)

4. Take time to consider this, and talk about it with your family and friends.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus and the health systems 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 Authorization 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 affiliate institutions that are not involved with this study. Do not use this form for VA research.]

* University of Colorado Denver | Anschutz Medical Campus
* University of Colorado Health
* Children’s Hospital Colorado
* Denver Health and Hospital Authority

The records that identify you, and the consent form and this authorization form signed by you may be looked at by others listed below who have a legal right to see that information:

[Delete any institutions that are not involved with this study. Add any others that are involved.]

* Federal offices such as the Office of Human Research Protection and the Food and Drug Administration (FDA) that protect research subjects like you.
* People at the University of Colorado Denver | Anschutz Medical Campus who are involved in research.
* People at the Institutional Review Board (IRB) responsible for reviewing this study.
* The study doctor and his/her team of researchers.
* [Insert sponsor name], who is paying for this research study.
* Officials at the institutions where the research is being 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 have legal authority to audit identifiable study records.]

Your information may be used and disclosed, to do the research, to study the results, and to make sure that the research was done right.

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 protected health information from the investigator. [If applicable include: To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.]

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 the consent form for this study and in this authorization form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver | Anschutz Medical Campus and its collaborators may not be covered by this promise and your information may be disclosed without your permission.

We will do everything we can to keep your records confidential, however, this 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, 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.

 [Add PI Name and Mailing Address]

If you agree to be in this study, you will receive a signed and dated copy of this authorization form for your records.

[The following section is for outside disclosures of research information that you will make. Include the name of any specific study-related person or group, external to the University, such as the Sponsor, outside laboratory or Contract Research Organization (CRO). Include recipients of information for optional research procedures. If there will be no outside disclosures of data, delete this section]

**The investigator (or staff acting on behalf of the investigator) will also make** all or some **of the following health information about you available to:**

* [Organization]

[Delete the following paragraph if not applicable.]

Some of the research procedures involve genetic testing or the use of your genetic information. Your genetic information will be used for research and will not be released to others with other information that identifies you. [Add if applicable.] Identifiable genetic information will be released to:

**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 Diagnoses, 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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[Delete this section if there are no optional study procedures.]

**HIPAA Authorization for Optional Additional Study Procedures**

In the study summary, 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 will be used for research and will not be released to others with other information that identifies you. [If applicable] Identifiable genetic information 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.

***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to authorize the use and disclosure of your protected health information as described above for this study and any optional studies you agreed to participate in via the consent form. By signing this authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

**Name of Subject**

**Signature of Subject (18 or older and able to consent) Date**

**Signature of Legally Authorized Representative with authority for Date**

**research decisions (if applicable)**

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**Authority of Legally Authorized Representative or Relationship to Subject (if applicable)**