**If your study provides payments or reimbursement of expenses are paid through funds at CHCO, the following paragraph must be in your consent.**

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.

**If the study has a section for reimbursement for out-of-pocket expenses, the following sentence will be added:**

Reimbursements are not subject to IRS regulations and will not be reported as income.

**HIPAA Language (modify the template as indicated below)**

The University of Colorado Denver (UCD) and its affiliated hospital(s) 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
* University of Colorado Hospital
* Children’s Hospital Colorado (Children’s Colorado)
* Denver Health
* National Jewish Health
* Veterans Affairs Hospital – Denver
* Other (*name; use this space for other* ***affiliated*** *institutions only, such as Barbara Davis Center, etc.*)

*[Add here]*:  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.