HIPAA Authorization for Research

Study Title: [Study Title and IRB #]

Principal Investigator: [Name]
[Name of main study site]
[Address of main study site]

Co-Investigator(s): [Name- or remove this line if none]

The purpose of this form is to seek your authorization (permission) for the Principal Investigator listed above and their research team to use and share your individual health information for the above study.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team. You will get a copy of this form.

What information will you use and share for the study?

If you give your permission and sign this form, the Principal Investigator and their research team will use and share information from your medical records and other information that could identify you.

For this study the research team will use and share any information from the marked boxes below:

☐ Research Record	☐ Genetic testing information
☐ Entire Medical Record	☐ Information about mental health diagnosis or treatment
☐ History & Physical Exams	☐ Information about drug or alcohol abuse, diagnosis or treatment
☐ Lab & Pathology Results	☐ HIV/AIDS testing information [Colorado's rules require health care providers and laboratories to report cases of HIV and AIDS to local CHHS offices.]
☐ Imaging Reports/Photos	
☐ Emergency Dept. Record	
☐ Financial records	☐ Other (describe): *explain here*

Why will this information be used and shared with others?

- To conduct the research study or case report described to you
- To improve the design of future studies
- To study the results
- To see if the research contributes to generalizable knowledge

Who is this information shared with?

We may share information that might identify you with:

- Government agencies that oversee research (like the U.S. Food and Drug Administration or the National Institute of Health).
- Other people who oversee research to make sure it is done safely and correctly (like staff or affiliates of the study sponsor, a drug/device manufacturer, or an IRB (Institutional Review Board)).
- The study sponsor or business partners who are involved in doing the research.

- For studies or procedures that are related to your medical care, study information may be placed in your medical record. Staff that sees your medical record as part of your care may be aware that you are/were in a research study.

What happens if I say no?

You do not have to sign this form. If you do not, you will not be able to be in the research study. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

May I change my mind later?

Your permission to use and share information for this study does not have an expiration date unless a time frame is described here: _____

At any time, you can tell us to stop using and sharing health information that identifies you. If you want us to stop, you have to tell us in writing. You can get the researcher's address by calling [###].

When we stop, no new health information identifying you will be used or shared. Information that has already been collected may still be used and given to others for limited purposes. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

Giving permission

By signing this form, I agree to allow the use and disclosure of my health information for the purposes described above.

Optional research activity: If there are optional research activities this box will be marked. If it is marked, you can choose if you want to allow your information to be shared for this activity or not. Your information will be shared for the optional activity only if you give permission by putting your initials on the line.

☐ *Add if applicable; otherwise, remove this section.* This research has an extra optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process.	*I agree to allow my information to be released for the optional research activities described.* _____ *(initials)*

Printed Name of Subject DOB of Subject

Signature of Subject or Authorized Representative Date Time

Relationship of Subject or Authorized Representative Date Time