Investigator's Institution

Address

Address

**"Name of Study"**

Investigator

PI's Phone Number

**Authorization for Use and Disclosure of Protected Health Information**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, give permission for name of covered entity

(Study participant name)

to give protected health information in my source records to PI, or to a member of his/her/their research team. I’m not required to sign this form to get services/health care/treatment, etc. Name of covered entity will only give my protected health information to the researchers if I sign this form.

**What information may be used and given to others?**

The study team will get your personal and/or medical information. For example:

* Past and present medical records
* Research records
* Records about phone calls made as part of this research
* Records about your study visits

**Who may use and give out information about you?**

The PI and the study staff. They may also share the research information with the sponsor of the research.

**Who might get this information?**

The sponsor of this research. “Sponsor” means any persons, agencies or companies that are:

* working for or with the sponsor, or
* owned by the sponsor.

**Your information may be given to:**

* The U.S. Food and Drug Administration (FDA),

1. Department of Health and Human Services (DHHS) agencies,
2. Governmental agencies in other countries,
3. Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
4. Washington State Institutional Review Board (WSIRB), and others who watch over the safety, effectiveness, and conduct of the research.

.

*[Add any other institutional/agency names.]*

**Why will this information be used and/or given to others?**

* To do the research,
* to study the results, and
* to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

**What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study.

**May I review or copy my information?**

Yes, but only after the research is over.

**May I withdraw or revoke (cancel) my permission?**

Yes, but this permission will not stop automatically.

*[or]*

This permission will be good until [date] *[required in CA, DE, IN, IL, WA, and WI].*

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the team. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**Do I have to sign this form in order to enroll or be eligible for benefits or treatment?**

Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans, or eligibility for benefits.

**Is my health information protected after it has been given to others?**

There is a risk that your information will be given to others, that may or may not be subject to HIPAA, without your permission.

For disclosure of DSHS records, insert the following: “My privacy rights are described in detail in the DSHS Notice of Privacy Practices for Client Medical Information (available at https://www.dshs.wa.gov/sites/default/files/forms/pdf/03-387.pdf)

Include if applicable:

To release the specific information listed below, you need to also write your initials next to the type of information. This is your specific permission for release of this information, which is required by Federal and state laws. The federal rules bar any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

\_\_\_\_\_\_\_\_\_\_ Sexually transmitted disease

\_\_\_\_\_\_\_\_\_\_ AIDS or HIV

\_\_\_\_\_\_\_\_\_\_ Behavioral or mental health/illness, including psychotherapy notes

\_\_\_\_\_\_\_\_\_\_ Drug or alcohol abuse, diagnosis, or treatment

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Study Participant Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Participant Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s Legally Authorized Representative (if required) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Representative’s Relationship to Study Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Person Obtaining Authorization Signature Date

*[If the authorization is signed by an individual’s legally authorized representative of the individual, a description of such representative’s authority to act for the individual must also be provided.]*