**General Instructions:**

* Please delete this page and the instructional text/green highlights throughout the document.
* **Text in this document is required and not editable in general.** ***Please include this text, do NOT edit it, and do not delete any of the text except as directed. Editing/deleting this text may put your study in violation of HIPAA or other privacy requirements.***
* Fill in the Header Information; do not modify information in the footer.
* Follow directions given throughout the form.

Permission to Use, Create and Share Health Information for Research

Study Title:

PI Name:

PI Contact Information:

The purpose of this form is to give your permission to the research team to create, use or share your protected health information (PHI). **Please read this form carefully**.

To be in this research study, you must sign this permission form. After reading this form, you can refuse to sign this form. If you do not want to sign this permission form, this will not affect the care and treatment you receive. You will also be asked to sign a research consent form that describes details about the research. If you have questions about this permission form or the research consent form, you can ask the research team at any time.

The word “you/your” in this form may refer to you or your child.

**What Will Happen with My PHI?**

If you join the study, we will keep your PHI confidential as provided by law.

You have certain privacy rights regarding your PHI. Only with your permission may we create, use, or share your PHI for this study. The following describes the types of PHI the study will create, use, or share, who may use it or share it, and the purposes for which it may be used or shared.

PHI may include things like:

* Past or future medical records,
* Research records, such as surveys, questionnaires, interviews, or self-reports about medical history,
* Medical or laboratory records related to this study, or
* Information specific to you like your name, address, birthday, ethnic origin, or identifying numbers like your social security number.

PHI may be created by, used by, or shared with:

* Researchers (such as doctors and their staff) taking part in this study here and at other centers,
* Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
* Other people or organizations involved with your health care,
* Review boards (such as Seattle Children’s Institutional Review Board), data and safety monitoring boards, and others responsible for overseeing the conduct of research (such as monitors),
* Governmental agencies like the U.S. Food and Drug Administration (FDA), the

Department of Health and Human Services (DHHS) and similar agencies in other countries, or

1. Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, or disability.

PHI may be created, used, or shared to:

* Study the results of this research,
* Check if this study was done correctly,
* Complete and publish the results of the study described in this form,
* Comply with non-research obligations (such as notifying others if we think you or someone else could be harmed), or
* Facilitate your health care.

**Can I Review My PHI?**

You may look at or copy the information that may be created, used or shared. However, for certain types of research studies, some of your PHI may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

**When Will My Permission Expire?**

Your permission for the creation, use or sharing of your PHI will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new PHI will be collected about you. However, information that has already been collected may still be used and shared with others.

Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your PHI will be banked as part of this study, it may be used in the future for other research. We will not ask for your permission prior to this future research.

(Note: Include the following paragraph if study includes treatment, care, or diagnosis)

**Will Information From This Study Be Put Into My Medical Record?**

We may also put information from this study in your medical records, including this form, because this study involves your care. Medical records have different rules than research records. Medical records may be seen by others involved in your care, such as doctors, insurers, and others as required by law.

**Are There Other Ways My PHI May Be Shared?**

We will follow privacy laws when creating, using, or sharing your PHI, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

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

Your permission is documented by signing this form below. If you decide that we cannot create, use and/or share your PHI, you cannot participate in this study.

Note: Only use the following language if the study (1) relies on medical records (or a patient’s health care provider) as a source of information about the treatment and/or diagnosis of one or more of the specially protected categories below; or (2) involves treatment and/or diagnosis of one or more of the specially protected categories below. For the following section, delete any types of information that do not apply to your study. If none apply, delete the whole section.

**Permission for Use or Sharing of Specific Information**

The creation, use, or sharing of specific kinds of information requires that certain individuals provide separate permission. Individuals who are within the age ranges below will complete this section. For minors under the age range(s) listed, the parent/legally authorized representative will complete this section. Mark your permission with your initials below if you agree to the creation, use, or sharing of the following information:

\_\_\_\_ Sexually transmitted infections including AIDS/HIV (age 14 and older)

Initials

\_\_\_\_ Medical conditions involving sexual or reproductive health concerns, and any associated Initials test results (age 14 and older)

\_\_\_\_ Behavioral or mental health/illness (age 13 and older)

Initials

\_\_\_\_ Drug or alcohol abuse (age 13 and older)

Initials

Note: Only use the following language if the study involves optional procedures.

**Permission for Creation, Use or Sharing of Your PHI for Optional Procedures**

This research includes optional procedures. The optional part(s) of this research is/are (list optional procedures here). You may participate in the main study even if you do not want to do the optional procedures. If you decide to take part in the optional procedures, we need your additional authorization to create, use, or share your PHI for the optional procedures. The same general confidentiality rules as discussed above will apply.

I permit the creation, use, and/or sharing of my PHI for the optional procedures.

Initials

If you wish to cancel your permission for the optional procedures, you can do this by notifying us in writing. Your permission for the research study overall will remain in effect unless you tell the study team to cancel your permission for the research study overall too.

**Permission**

I have read this form describing how PHI will be used. I have had a chance to ask questions about the use of PHI and I have received answers to my questions.

By signing this form, I agree to the creation, use, and/or sharing of my PHI for the purposes of this research study. I will be given a copy of this signed form.

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*Printed Name of Research Participant*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Research Participant (if participant is 18 years or older)*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Parent or Legally Authorized Representative*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Parent or Legally Authorized Representative (if participant is younger than18 years)*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*

**Researcher Obtaining Authorization**

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Printed Name of Researcher Obtaining Parental Permission or Consent*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Signature of Researcher Obtaining Parental Permission or Consent*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date Time*