**[Instructions and optional language appear in [brackets]]**

**[Re Confidentiality and Privacy]**

**[Do not edit or delete the text in this section. Exception: Text in green in this section is optional if the study does not involve PHI under HIPAA regulations.]**

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

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following describes the type of information 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.

This information 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, and
* Information specific to you like your name, address, or birthday

This information may be 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,
* Review boards (such as Schulman IRB), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
* Governmental agencies like the U.S. Food and Drug Administration (FDA) and the

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

1. Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
2. If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

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

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

There is no time limit for the use or sharing of your information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your information 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 information will be collected about you, but information that has already been collected may still be used and shared with others.

**[Include if study includes treatment, care, or diagnosis]** We will 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. They are permanent and may be seen by others involved in your care, such as doctors, insurers, and others as required by law.

The use or sharing of your information will follow privacy laws, 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 would not be used.

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

**[Insert the following yellow highlighted section if appropriate. Delete the types of** **information not needed for this research.]**

The following section in *italics* will be completed by different individuals depending on the age of the minor participants. Because adolescents may agree to the use or sharing of certain kinds of information on their own, adolescents fitting the criteria below will complete this section for themselves. For all other minor participants, the parent/legally authorized representative providing permission will complete this section on behalf of the child.

*Please consider whether we may use or share the information listed below for this research. If you agree, please mark your permission with your initials.*

\_\_\_\_ *Sexually transmitted disease (14 and above)*

\_\_\_\_ *AIDS or HIV (14 and above)*

\_\_\_\_ *Medical Conditions involving sexual or reproductive health concerns, and any associated test results (14 and above)*

\_\_\_\_ *Behavioral or mental health/illness (13 and above)*

*\_\_\_\_ Drug or alcohol abuse, diagnosis, or treatment (13 and above)*

**[Note that the following HIPAA language in blue is not required unless the study has optional procedures.]**

**Permission for Use or Sharing of Your Information for Optional Procedures**

This research includes optional procedures. The optional parts of this research are: **[list** **optional procedures]**. You may choose whether you want to be a part of these optional procedures. No matter what you choose you may still participate in the research.

Because choosing to participate in the research is separate from choosing to participate in the optional procedures, we need your separate permission to use or share your information for the optional procedures.

The same general rules as discussed above will apply to the use and sharing of your information for the optional procedures as for the research. The information will relate to you and your health, it may be used by or shared with others involved in this research study or in future research studies, and its use or sharing will be consistent with the purpose for which it was collected.

I (self, parent or legally authorized representative) permit the collection, use, and sharing of my/my child’s health information 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.

**[Re Cost]**

**[Re Injury]**

**[One of the statements below is required. Select the appropriate required phrase based on your study. Who pays for research related injuries depends on risk, who is sponsoring the study, and whether the study provides a potential for direct benefit (e.g., treatment, diagnosis) to the participant.]**

**[For all minimal risk (45 CFR 46.404) studies, please use the following language:]**

If you think you have been harmed from this study, please call the study doctor at the telephone number listed on page one of this consent document.

**[For greater than minimal risk studies where Seattle Children’s compensation program applies (applies if the study does not have an industry sponsor and does not provide the potential for direct benefit):]**

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.

You would NOT need to pay for this treatment and neither would your insurance company. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher, if you think that you have been injured as a result of taking part in this study. You can call him/her at the telephone number listed on page one of this consent document.

**[For studies where families or third party payers are responsible (usually when the study offers the prospect of direct benefit):]**

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed. No funds have been set aside for this treatment.  You or your insurance company would be billed for the treatment.

It is important that you tell the Principal Researcher, if you think that you have been injured as a result of taking part in this study. You can call him/her at the telephone number listed on page one of this consent document.

**[For industry-sponsored studies involving Category B devices:]**

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.

You or your insurance company MAY need to pay for this treatment.  Neither you nor your insurance company would need to pay for the cost of treatment needed because the study device failed or malfunctioned. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher, if you think that you have been injured as a result of taking part in this study. You can call him/her at the telephone number listed on page one of this consent document.**.**

**[For all other industry-sponsored studies:]**

If you were injured as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed.

You would NOT need to pay for this treatment and neither would your insurance company. This is the only compensation offered for study-related injuries. It is important that you tell the Principal Researcher, if you think that you have been injured as a result of taking part in this study. You can call him/her at the telephone number listed on page one of this consent document.

**[Re Payments for Participation]**

**[If payment is involved, researchers at Seattle Children’s are expected to follow Seattle Children’s Office of Research Finance Policy 004 (ORF-004) for participant payments.]**

**[Include the following:**

* **Amount of payment that will be given,**
* **The method for providing payment (ClinCard/check/egift card),**
* **Which individual (parent or child) will receive it**
* **When the payment will be given]**

**[Example if you are providing Greenphire/ClinCards for Seattle Childrens Hospital:**

Additional Greenphire language for Seattle Children’s Hospital.

A company called ‘Greenphire’ will manage travel reimbursement and a ClinCard, which is a debit card, will be provided to you. When you complete a visit, the amount outlined in this Informed Consent Form will be automatically approved and added onto your ClinCard. The study staff will provide you with additional information about how the ClinCard works. In order for Greenphire to be able to reimburse you using the ClinCard, Greenphire will collect the following information about you: your name (required), birth date (required), address (required), social security number (required for IRS reporting) and contact details (cell phone number and/or email address – optional). By choosing to use the ClinCard service you are authorizing the release of this information to Greenphire.

Payment for taking part in a research study is considered taxable income. If this payment is more than $600.00 in any one calendar year Greenphire is required to report this to the Internal Revenue Service (IRS). For this purpose Greenphire requires your social security number. The study sponsor (Vertex) will not have access to your social security number. Income will be reported using a 1099 (Miscellaneous Income) form. A copy will be sent to you and to the IRS. Please be aware that all reimbursements such as parking, meal vouchers, hotel, transportation, etc. do not count towards the $600 limit and will not be taxed as income.

 **[Note: You may be able to get an exception to the requirement to collect names, addresses, and social security. See ORF-004 for more information. If you do not have an exception, then the next section is required.]**

**The IRS has certain rules about paying people who take part in research studies.  If you took part in this study, we would ask you to provide your name, mailing address, and social security number so we could pay you.**

**You can be in this study even if you do not give us this information. If you decide not to give us this information, you would receive no payment.**

**The payments you would receive for being in this study might be taxable. Institutions are required to report to the IRS study payments totaling $600 or more made to anyone in any year.**