RESEARCH SUBJECT INFORMATION AND CONSENT FORM

## TITLE:

## PROTOCOL NO.:

 WCG IRB® Protocol #

## SPONSOR:

## INVESTIGATOR:

## SITE(S):

## STUDY-RELATED

## PHONE NUMBER(S):

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Add the following statement only if the study protocol expressly allows the enrollment of subjects not capable of consenting for themselves:A person who takes part in a research study is called a research or study subject. As the legally authorized representative, you are being asked to provide consent on behalf of the study subject because the subject is not able to provide such consent. If the study doctor determines at a later time that the subject is able to provide consent, the subject will be asked to do so. The words “you” and “yours” in this consent form generally refer to the study subject, however, there may be some instances where “you” refers to whomever is providing consent.

## SUMMARY

Insert submitted or previously approved text

## PURPOSE OF THE STUDY

Insert submitted or previously approved text

## PROCEDURES

Insert submitted or previously approved text

## RISKS AND DISCOMFORTS

Insert submitted or previously approved text

## Other Risks

Insert submitted or previously approved text

## NEW INFORMATION

Insert submitted or previously approved text

## BENEFITS

Insert submitted or previously approved text

## COSTS

For all research studies, you must describe any additional costs to the participant or their insurance that may result from participation in the study. To accomplish this, choose the language below that is most appropriate to your study. **Inclusion of one of these statements is required.**

1. For a study in which there are no costs to the participant that may result from involvement in the study (unless it meets the criteria in #3 of this section), use the following language:

If you take part in this study, there will be no cost to you and no cost to your insurance company for the research procedures.

1. For a study in which there are costs to the participant that may result from participation in the study (unless it meets the criteria in #3 of this section), add the following language:

If you take part in this study, you or your insurance company may be charged for: Describe the services that the participant or their insurance provider may be charged for as a result of study participation.

1. For a study that involves research services and medical services:

This study is a clinical trial that involves two types of services. Some services are related to the research. Other services are related to your usual medical care.

Services related to the research are done only for the purpose of the study. These include:

Clearly identify these services by referencing when they take place (e.g., 1st visit).

* Research Service
* Research Service

Choose the appropriate statement below about who will be charged for these research services.

There would be no cost to you and no cost to your insurance company for these research services.

Or

You or your insurance company may be charged for these research services.

Include an explicit statement about who is financially responsible for the experimental components of the study (drug, administration of drug, device, implantation of device).

Services related to your usual medical care are part of your routine care. You or your insurance company would be charged for these services. If you join the study, costs to you would include your usual insurance deductibles and co-payments. All of your insurance company’s usual rules would apply.

When applicable, include a statement about when pre-approval will be required from insurance companies (likely for inpatient stays, surgery, devices, and any other high-cost items).

**PAYMENT FOR PARTICIPATION**

Insert submitted or previously approved text.

If no payment is involved:You will not be paid to take part in this research study.

If reimbursement is involved:The study will reimburse you for out-of-pocket costs to you. This would include:

* Transportation costs to the hospital or clinic for study tests and visits.
* Cost of meals during the time of your study visits.
* Cost of child care during the time of your study visits.

**Important:** You will need to give us receipts that clearly show your costs.

If payment is involved:

* If the parent/LAR will be the one receiving the payment on behalf of their child, make sure to update the language accordingly.
* You need to follow the Research Participant Payment Requirements, 13679 Policy. This policy is available in PolicyStat. See also HRP-316 Payments.
* Be sure to keep all identifying information collected solely for payment reasons, including social security number, separate from the research records. It is suggested that you destroy such information after sending it to the Finance Department or after the participant has received payment.
* If you are doing work with Department of Defense Research or prisoners, there may be additional language required here.
* Include the following information:
	+ The amount of payment that will be given,
	+ The method for providing payment (can be stated generally as noted below)
	+ When the payment will be given
	+ The anticipated prorated payment (if any).

If payment is involved:  To thank you for taking part in the study we will give you $X.  We will work with you to choose a form of payment that will work best for you. We will give you separate information about how some forms of payment work if applicable.

If payment is involved and study is moving from ClinCard to Advarra Card:  To thank you for taking part in the study we will give you $X.  You will receive the payment on a reloadable pre-paid card. We will give you separate information about how the reloadable pre-paid card works.

If payment is involved and study will use just one form of payment: To thank you for taking part in the study we will give you $X.  You will receive the payment [on a e-gift card, etc.]. We will give you separate information about how [the e-gift card, etc.] works.

If providing ClinCards (Revise as needed. If participants would be charged to replace a lost ClinCard, they must be informed in this section):

To thank you for taking part in the study we would give you $X after each study visit you complete. You will receive the payment on a reloadable debit/gift card called a ClinCard. The study staff will provide you with additional information about how the ClinCard works. Costs for replacing a lost or stolen ClinCard will be your responsibility. The cost to replace the ClinCard is $7.

**If you take part in this study, we would ask you to provide your name, address, and social security number so we could pay you. Information about you, including your name, mailing address, and social security number, may be shared with an external vendor to facilitate payment.** **If you’re not using an external vendor to facilitate payment, you can remove the preceding statement. If you think during the life of the study you will ever use an external vendor to facilitate payment, you should leave the statement in the form.**

**The payments you would receive for being in this study may be taxable. Seattle Children’s is required to report to the IRS study payments of $600 or more made to anyone in any year.**

**If all or some participants will be Seattle Children’s employees include:Payments made to Seattle Children’s employees for study participation must be paid via the individual’s paycheck and will be taxed. You will be asked to provide your employee ID so the payment can be made. Your employee ID is only used for payment purposes.**

**You can be in this study even if you do not give us your information, but you would not receive payment.**

Incentives paid to participants who are Seattle Children’s employees are tracked for IRS requirements via payroll. If the study involves ONLY payments to employees, then name, mailing address, and social security number do not need to be collected for payment purposes (the applicable language can be removed from above if this is the case).

See Research Participant Payment Requirements, 13679 Policy about the need to collect names, addresses, and social security.

**ALTERNATIVE TREATMENT**

Insert submitted or previously approved text

**CONFIDENTIALITY**

Please note that the terms you include in this section will likely be considered binding on your study plans, so they should be chosen carefully. Any change to these terms during your study will likely result in the need for re-consent of study participants or consideration of a waiver of consent elements.

If you join the study, we will do our best to make sure that information about you is kept confidential.

Insert plan to maintain confidentiality (example text provided): We will store all of your research records in locked cabinets and/or secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person’s name or any other identifier to their study number is stored separately in a locked cabinet or on a secure computer file. If you intend to share data with collaborators external to Seattle Children’s, include the following statement or something similar (the IRB recommends that you do not list the collaborators specifically): We will share data with external investigators who are collaborating on the study.

These are some reasons that we may need to share the information you give us with others:

* If it is required by law, including suspected child abuse, elder abuse, intent to harm yourself or others and communicable diseases.
* If the author of the research plan (the research sponsor) or any persons or companies working for or with the research sponsor needs the information.
* Study records are sometimes reviewed to make sure studies are done correctly and safely. These reviews can be done by the research team, hospital staff, government staff or others with the responsibility to make sure studies are done correctly and safely for participants. If a review of this study is done, study records that include your information may be viewed. The reviewers will treat your information as confidential. The reviewers will not use your information for immigration reasons or to put you at legal risk.
* Include for studies regulated by the U.S. Food and Drug Administration: For this study, the U.S. Food and Drug Administration (FDA) may review study records that include your information. Names are not usually required by the FDA. The reviewers will treat your information as confidential.
* Include for studies that will place research information/consent form in the participant clinical/medical record(s) (required for studies involving treatment, care, or diagnosis): For this study, choose: your participation in this study will be noted in your medical record(s) OR a copy of this form will be placed in your medical record(s). 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.

If results of this research are published, we would not use information that identifies you without your permission.

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.

Individuals who are within the age ranges below will complete this section. For minors under the age range(s) listed, the parent/LAR will complete this section. Mark your permission with your initials below if you agree to the creation, use, or sharing of the following information that will have the same privacy protections that are described above:

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

Initials

\_\_\_\_\_\_ Medical conditions involving sexual or reproductive health concerns, and any Initials associated 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

For studies involving creation, use, or sharing of PHI include:

This study will also involve a type of information about you called Protected Health Information (PHI). PHI refers to information that is about your health and that could identify you. Researchers (such as doctors and their staff) taking part in this study here and at other centers will only create, use, and share your PHI for this research study with your permission.

PHI may include:

**Principal Investigator:** Please note that the terms you include in this section can be included/omitted based on the information involved in your study, but they will likely be considered binding on your study plans, so they should be chosen carefully. Any change to these terms during your study will likely result in the need for re-authorization or consideration of waiver elements.

* 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 or identifying numbers like your social security number.

PHI may be created, used, or shared to:

**Principal Investigator:** Please note that the terms you include in this section can be included/omitted based on the information involved in your study, but they will likely be considered binding on your study plans, so they should be chosen carefully. Any change to these terms during your study will likely result in the need for re-authorization or consideration of waiver elements.

* Study the results of this research;
* Check if this study was done correctly and safely;
* 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.

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

**Principal Investigator:** Please note that all of these terms need to be used.

* The author of the research plan (the research sponsor) or any persons or companies working for or with the research sponsor;
* Review boards, data and safety monitoring boards, and others responsible for overseeing the conduct of research. Study records are sometimes reviewed to make sure studies are done correctly and safely. These reviews can be done by the research team, hospital staff, government staff or others with the responsibility to make sure studies are done correctly and safely for participants. If a review of this study is done, study records that include your PHI may be viewed. The reviewers will treat your PHI as confidential. The reviewers will not use your PHI for immigration reasons or to put you at legal risk;
* Other people or organizations involved with your health care;
1. Public health authorities to whom we are required by law to report PHI for the prevention or control of disease, injury, or disability.

You have the right to look at or copy your PHI 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 records.

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 created or collected about you. However, PHI that has already been created or 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 stored 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.

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 PHI as part of this study may share it with others without your permission if doing so is permitted by law.

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

**Permission for Creation, Use, or Sharing of PHI for Optional Procedure(s)**

Participation in any research study is voluntary. If you agree to participate in this research study, there are some part(s) of the study you will be asked to do. There are other part(s) of this study that you can choose not to do and still participate in the rest of the study. These are called Optional Procedure(s). For this study, the Optional Procedure(s) are:

* briefly list here

If you decide to do these part(s) of the study, we need your additional permission to create, use, and share your PHI for these part(s) of the study. The same confidentiality rules and privacy rights discussed above apply here.

 I allow the creation, use, and sharing of my PHI for the Optional Procedure(s).

Initials

Remember that you can always change your mind about doing any part of the study. Your choice will not impact your medical care or benefits outside of the study. You can cancel your permission for these Optional Procedure(s) by telling us in writing. If you do this, you will still be in the overall research study unless you tell us to cancel your overall permission too.

Include the following language if the research has been issued a Certificate of Confidentiality (CoC) by the federal government. Please note that if research is funded by certain federal agencies (e.g., NIH, CDC, etc.) it is automatically issued a CoC. It is the responsibility of the PI to know if their study has a CoC or other equivalent statutory protection.

**Certificate of Confidentiality**

We have a Certificate of Confidentiality from [insert name of federal agency] for this research.  The Certificate means we cannot be forced to give out information about you, unless you say it is okay, even if we are asked to by a court of law.  It’s not likely that someone would ask us to give out your information, but this Certificate helps protect it.  Even with the Certificate, your information could still be given out in the situations described above in the “What about my confidentiality and privacy?” portion of this form and in these additional situations:

* For your medical care;
* For other research if allowed by federal regulations;
* If the funder of the research needs the information;
* You or a family member could share information about you or your part in this research.

## COMPENSATION FOR INJURY

One of the statements below is required. Select the appropriate required phrase based on your study:

1. For all minimal risk studies, please use the following language:

If you think you have been harmed from this study, please call \_\_\_\_\_\_\_\_.

1. For greater than minimal risk studies that do not provide the potential for direct benefit and do not have an industry sponsor:

If you are injured as a direct result of this research study, Seattle Children's Hospital will provide treatment, or will 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      .

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

If you are injured as a direct result of this research study, Seattle Children's Hospital will provide treatment or 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 the him/her at       .

1. For industry-sponsored studies involving Category B devices:

If you are injured as a direct result of this research study, Seattle Children's Hospital will provide treatment. or refer you for treatment if needed.

You or your insurance company MAY need to pay for this treatment.  Neither you nor your insurance company will be billed 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      .

1. For all other industry-sponsored studies:

If you are injured as a direct result of this research study, Seattle Children's Hospital will provide treatment or 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      .

## VOLUNTARY PARTICIPATION AND WITHDRAWAL

Insert submitted or previously approved text

If appropriate

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## SOURCE OF FUNDING FOR THE STUDY

Insert submitted or previously approved text

## QUESTIONS

Contact *[name]* at *[number(s)]* for any of the following reasons:

* if you have any questions about this study or your part in it,
* if you feel you have had a research-related injury or a bad reaction to the study drug, or
* if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

 WCG IRB

Telephone: 855-818-2289

 E-mail: clientcare@wcgclinical.com

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

## CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights. Keep the following sentence if PHI is used in the study. If no PHI is used, delete this sentence: You permit the creation, use, and sharing of your and/or your child’s health information for the purposes of this research study as described in the “Confidentiality” section above.

Example signature block for research involving adults able to consent, minors, and adults who lack the capacity to consent when applicable. Assent requirements may change depending on WIRB’s study determinations and whether the sponsor provides a separate assent form:

***Consent and Assent Instructions:***

*Consent: Subjects 18 years and older must sign on the subject line below*

*Consent is provided by the Legally Authorized Representative for adult subjects unable to consent*

 *For subjects under 18, consent is provided by the parent or guardian*

*Assent: Is not required for subjects 6 years and younger*

 *Verbal assent is required for subjects ages 7 through [14] years using the Assent section below [and the Information Sheet for Children].*

 *Verbal assent is required for subjects ages [15] through [17] years using the Assent section below [and the Information Sheet for Adolescents].*

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

Subject Name (printed)

**CONSENT SIGNATURE:**

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

Signature of Subject (18 years and older) Date and Time

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

Signature of Legally Authorized Representative, Date and Time

Parent or Guardian (when applicable)

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

Authority of Subject’s Legally Authorized Representative or Relationship to Subject

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

Signature of Person Conducting Informed Date and Time

Consent Discussion

**ASSENT SECTION For Subjects Ages [7] - [17]:**

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject’s decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject’s physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

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

Signature of Person Conducting Date and Time

Assent Discussion

Statement of Parent or Guardian:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

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

Signature of Parent or Guardian Date and Time

**ASSENT SIGNATURES, For Adult Subjects with a Legally Authorized Representative:**

Assent:

For adult subjects who have a legally authorized representative, I confirm that:

* I have explained the study to the extent compatible with the subject’s understanding, and the subject has agreed to be in the study.

OR

* The subject is not able to assent due to lack of mental capacity.

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

Signature of Person Conducting Assent Discussion Date and Time