Informed Consent Version:

Children's Healthcare of Atlanta

Consent Summary

Short Title:	**PI:**

If this form is being read by the parent or legal guardian, the term "you" refers to "your child."

You are being asked to take part in a research study about (*insert brief, general description of study – i.e., this is a research study to find out if drug X is safe and to determine the most effective dose of the drug)*

Why is this study being done?

By doing this study we hope to learn *insert primary purpose as briefly as possible. If the study involves an FDA-regulated product (drug, device or biologic), indicate whether the test article is being used consistent with labeling indications or if the use or article is investigational.*

What will I be asked to do?

If you agree to join the study, you will be asked to (*insert number of visits). Your participation will last about (insert duration in hours, days, months or years).*

What are the reasons you might choose to participate in this study?

State the most important reasons (i.e., potential benefits) a person may want to volunteer to participate in the study. For a complete description of benefits, refer to the section titled "What are the possible benefits of being in this study?"

What are the reasons you might choose not to participate in this study?

For treatment/intervention studies: We do not know if (*insert study product/behavioral intervention*) would help (*prevent or treat name of disease/condition)* and could even make your disease/condition worse. (Insert name of study product/behavioral intervention) could cause side effects such as (insert a few significant examples). For a complete description of risks, refer to the section titled "What are the possible risks to being in this study?".

For studies that do not involve treatment/intervention: State the most important reasons/risks why a participant may NOT want to volunteer for this study. For a complete description of risks, refer to the section titled "What are the possible risks to being in this study?"

Discuss alternative treatment/procedures that might be advantageous to the subject. For a complete description of alternate treatment/procedures, refer to the section titled "What are the alternatives to being in this study?".

What if you have questions, suggestions or concerns?

The person in charge of this study is (*insert PI name*). If you have questions, suggestions or concerns regarding this study or if you want to withdraw from the study you can contact (*insert PI name and contact information*). *For greater than minimal risk studies, include a way to contact the study team after hours (i.e.,dedicated pager, dedicated cell phone number or other reliable 24 hour contact option and deferral to 911 if deemed necessary.*

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Following is a more complete description of the study and what you will be asked to do. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. Please read this form carefully, asking any questions you have. You do not have to join this study. If this is a treatment study, you can receive standard methods to prevent or treat your condition instead of participating in this study.

If you have questions, suggestions or concerns about your rights as a participant in this research, contact the Children's Healthcare of Atlanta Institutional Review Board (IRB) at 404-785-7477 or irb@choa.org.

Informed Consent Version:

Children's Healthcare of Atlanta, Inc. and Children's Healthcare of Atlanta at Hughes Spalding Hospital
Consent and Authorization to be in a Research Study

Title:

Principal Investigator:

Sponsor's Name: *If the study is not funded, delete this section*
General:

- You are being asked to be in a research study. This form explains what would happen if you join this research study.
- Taking part in this study is voluntary and it is entirely your choice.
- If you take part in this study, you may stop being in the study at any time.
- Your decision to join or not join the study will not affect your current or future medical care at Children's.
- It is important that you read and understand this form in order to decide whether or not you want to be a part of this study. Take as much time as you need.
- It is also important that you ask any questions that you may have and that you understand all the information in this form.

Why is this study being done?
Guidelines:
- *Describe the purpose(s) and give a description of the research*
- *An explanation of why the subject is being asked to volunteer*
- *Give number of anticipated subjects at Children's and nationwide, if applicable*
- *Explain how individuals are identified and selected for this research study*
- *Include basic eligibility criteria*
- *If this study includes an investigational drug or device, include the following required statement* "This study involves testing an investigational (drug/device). This means the (drug/device) has not been approved by the Food and Drug Administration (FDA). Information from this research will help determine whether the (drug/device) should be approved by the FDA in the future."

What will happen to you in this study?

Guidelines:
- *Provide a detailed, chronological description of all treatment and procedures to be performed.*
- *State where the research will be conducted (e.g., where will the subject be seen).*
- *If the study involves random assignment, explain randomization in lay terms (for example, "like flipping a coin, drawing straws, etc.").*
- *Discuss any drugs or devices used in the study.*
- *If the study involves questionnaires, include a brief description of the types of questions that will be asked.*
- *Experimental procedures must be stressed and very clearly distinguished from the non-experimental procedures (routine care).*
- *If blood or spinal fluid is drawn, indicate the amount in lay terms (teaspoons). Distinguish between blood drawn at each visit and the total amount of blood to be drawn for the entire study.*
- *If placebo is involved, explain this in lay terms (i.e.,the placebo does not contain any medicine and is not expected to have any impact on your health).*
- *Provide a full explanation of all responsibilities and expectations of the subject.*
- *If the protocol includes a biological component which requires that specimens are sent to other researchers include the following:*

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1. *State whether the samples are strictly for research purposes and what will happen to the sample after the research is completed.*
2. *If the samples are to be banked for future research, provide check boxes for the subject to agree to or not to agree to future unknown research.*
3. *State whether the subject can opt-out at a later date (dependent on whether samples are identified* or *not) and how the subject may accomplish that.*
4. *State whether or not results from this research will be available to the subject.*

How long will you be in this study?

Guidelines:

- *Indicate how much of the subject's time will be involved at each visit.*
- *State how long the subject's participation in the study will last.*

What are the possible risks to being in this study?

General Risk Guidelines:

- *Inform the subject of all foreseeable risks, side effects or discomforts for all study procedures. Those described should include any foreseeable physical, privacy, social, economic and psychological risks. Include the likelihood of side effects and address the reversibility of side effects or adverse reactions. Describe what care has been taken to mitigate risks. Additionally, include the following sentence to address unforeseeable risks:* Due to the investigational nature of this study there may be risks, discomforts or side effects that are not yet known and there may be additional costs that result from participation (i.e., extended hospitalization).

- *If blood is drawn state the following:* There may be slight pain when the arm is stuck with the needle. A bruise may be left at the spot where the arm is stuck. There is a slight chance of swelling of the vein and/or blood clots, but this is extremely rare.

- *Any risks to the subject or to a fetus if a female subject becomes pregnant while participating in the study must be stated. Risks or side effects that are known or may be currently unforeseeable should be described and steps which should be taken by the patient to avoid such risks. State what steps are required to insure that subject is not pregnant, what steps the subject should take to avoid pregnancy, and what the subject should do if she discovers she is pregnant and who needs to be notified.*

- *Include the following statement if a study involves pregnancy testing:* Pregnancy testing will be performed on you for this study. The results of the pregnancy test are confidential. Results will be given to the participant by one of the study nurses or doctors in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. Children's policy is that we would not tell the parent or guardian of a positive pregnancy test without the child's permission. However, under certain circumstances, we might be compelled to reveal this information. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to inform the parent or guardian of the participant of a positive pregnancy test. During the study, if you have a positive pregnancy test, we must withdraw you from the study. This means that even if we do not reveal the results, parents or guardians may suspect that you are pregnant despite efforts to maintain confidentiality.

- *Required wording if a study involves focus groups:* Participation in research may involve a loss of privacy; however, your records will be handled as confidentially as possible. The researchers will ask you and the other people in the focus group to use only first names during the group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussion private. Only the study team will have access to your study records and any recordings. No individual identities will be used in any reports or publications that may result from this study.

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- *Wording if the study includes video or audio recordings:*
  Indicate who will have access to your records. Explain what will happen to the recordings (i.e., transcribed and then destroyed or transcribed and kept until completion of the study, etc.).

- *Required wording if there is a greater chance of uncovering child abuse than usual:* If, during your participation in this study, the researcher has reasonable cause to believe that previously unreported abuse is occurring, he/she must comply with state law by filing a child abuse report with the Division of Family and Children Services. Study material might be court ordered for use in a custody or other court hearing. The researcher will make every reasonable effort to protect the confidentiality of the information, though it is possible that a civil or criminal court might demand the release of material.

- *Required wording if there is a greater risk of discovering suicidal risk:* If, during the completion of this study, we have reason to believe that you are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions and would not be able to assure confidentiality.

MRI Information (Include appropriate section as applicable)

- *Required wording if Generic MRI is a research procedure and not standard of care:* MRI is generally considered a harmless imaging technique because it does not involve exposure to ionizing radiation such as x-rays. There are however some risks with MRI that are easy to avoid but which you should be aware of. These potential risks very rarely cause harm when MRI is performed within established guidelines by people who are trained.

MRI uses a powerful magnet to make images. Therefore, persons with metal implants, such as certain types of surgical clips or pacemakers should not have an MRI. Other metal objects such as keys, pocket knives, or some types of jewelry must be removed prior to entrance in the magnet room. These objects can be pulled towards the magnet at very high speeds and can cause serious injury. You will be screened for such objects. In addition to a large magnet, the MRI scanner also uses radio frequency waves that can, on rare occasions, cause a mild warming sensation similar to what you feel on a warm day at the beach. The MRI scanner makes loud banging noises during the scanning session. During the MRI study, you will be provided with earplugs to reduce the noise heard from the scanner. It is also possible that the magnetic fields in the scanner can cause mild nerve and muscle twitching in the arms and legs. Such effects are extremely rare, but possible. Some people simply find it uncomfortable and/or claustrophobic to lie in the small space of the MRI scanner. If during the MRI, you get nervous or upset, the procedure will be stopped. Although there are no known long-term harmful effects from having an MRI scan performed, it is always possible that there are long-term effects that are not presently known.

- *If sedation is or may be required for the research MRI, include the following statement:* This study requires sedation so you sleep during the MRI scan. .
  - *Describe the agent used for sedation and any risks/contraindications of this agent*
  - *State how the agent will be administered*
  - *State how long participant will be under sedation*
  - *State who will monitor the participant and how*
  - *State the plan for recovery and an estimate of the time for full recovery and how recovery will be assessed*

When sedation is performed, wires are attached to you to monitor your breathing and heart rate during the procedure. On very rare occasions, the presence of such wires has resulted in burns at the site of skin contact. Proper placement and use of the wires greatly minimizes this risk and the technologists have been trained in this procedure so that the probability of a skin burn from the wire contacts is very small.

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- *Additional required wording for research MRI with Contrast:* IV (a needle inserted into your body with a tub attached to a bag of liquid) with contrast media (liquid that can be seen inside your body during imaging) is required for this study.

Specify the name and active ingredient of contrast media to be used in this study (i.e. gadolinium).

In some rare circumstances, patients may have an undesired reaction to the medium, such as an allergic reaction of hives, or in very rare circumstances, difficulty breathing. There is also the possibility of leakage of the injected contrast medium into the surrounding tissue (extravasations) that can cause reddening, burning, or scarring, and if a substantial amount leaks into the surrounding tissue, a consultation with plastic surgery may be required. Patients with chronic kidney disease should be excluded from this intervention.

- *Additional required wording for Cardiac research MRI:* For MRI studies of the heart, some additional devices are used which allow for us to generate high quality images of the heart but which also require wire attachments to your body, primarily on your chest. On very rare occasions, the presence of such wires has resulted in burns at the site of skin contact. Proper placement and use of the wires greatly minimizes this risk and the technologists have been trained in this procedure so that the probability of a skin burn from the wire contacts is very small.

Genetic Information (Include appropriate section as applicable)

- *Required language for all studies that obtain genetic information:* The Genetic Information Nondiscrimination Act (GINA) is a federal law that protects against genetic discrimination. This law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. For more information about GINA, please see: http://www.eeoc.gov/laws/types/genetic.cfm. This law does not protect you from being discriminated in life insurance, long-term care insurance, or from employers with fewer than 100 workers.

  In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

  In the State of Georgia, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

- *Required wording if genetic testing (involving proband only with known disease or disorder or condition (e.g., no risk of uncovering non-paternity, and no intention to discover a genetic disorder unknown to the patient, family or insurer):* There may be slight pain when the arm is stuck with the needle for a blood draw. A bruise may be left at the spot where the arm is stuck. There is a slight chance of swelling of the vein and/or blood clots, but this is extremely rare."

- *Required wording if genetic testing (involving proband only with known disease or disorder or condition (e.g., no risk of uncovering non-paternity, but a potential risk of discovering a genetic variation or condition unknown to the patient, family or insurer):* There may be slight pain when the arm is stuck with the needle for a blood draw. A bruise may be left at the spot where the arm is stuck. There is a slight chance of swelling of the vein and/or blood clots, but this is extremely rare.

There might be social and economic disadvantages, which can be associated with the gathering of genetic information. You should understand that the testing might find an inherited defective gene, which puts you or a relative at risk for a genetic disorder in the future. Genetic information divulged to the wrong source, could affect you and your family if an insurance company or employer acquired this genetic information. We will do our best to keep all information confidential and only with your permission or as required by law would we make this information available to others.

- *Required wording if genetic testing (involving proband and family members (e.g., risk of uncovering non-paternity and a potential risk of discovering a previously unknown disease or risk for disease in the proband or in family members):* There may be slight pain when the arm is stuck with the needle for a blood draw. A bruise may be left at the spot where the arm is stuck. There is a slight chance of swelling of the vein and/or blood clots, but this is extremely rare.

  There might be social and economic disadvantages, which can be associated with the gathering of genetic information. You should understand that the testing might find an inherited defective gene, which puts you or a relative at risk for a genetic disorder in the future. Genetic information divulged to the wrong source, could affect you and your family if an insurance company or employer acquired this genetic information. We will do our best to keep all information confidential and only with your permission would we make this information available to others.

  You may feel anxious about the possibility of carrying an altered gene that places you at risk or that may be passed on to children. If these feelings arise at any time during the study, you can contact the study team and arrange to speak with a genetic counselor.

  Because we are testing family members, we may detect instances of non-paternity or adoption. If you wish, you may let us know in confidence if this is a possibility, since it may otherwise interfere with our analysis. In all cases, this information will be kept in the strictest confidence and will not be divulged to anyone, except as required by law.

- *Required wording if reporting of Research Results/CLIA Statement*: "Because we are a research laboratory and not a clinical laboratory (lab) with certified procedures for reporting patient results, we cannot directly release results from this study to you. If we obtain information that we think might be significant to your family (e.g., identification of a mutation that has caused the disease disorder or condition we are studying), we may be able to have these results confirmed by a CLIA-certified clinical lab. A CLIA lab is a lab that is authorized to release results from patient's tests for clinical and diagnostic purposes. There will most likely be a charge associated with this testing which will vary depending on the lab. Most CLIA labs will ask for fresh blood samples in order to ensure the accuracy of the results. If your results are confirmed, they will be reported to your doctor and made available to you with proper genetic counseling. Please indicate below whether or not you wish to be informed if results become available. If you choose to be contacted, we can only do so through your own healthcare provider. Therefore, please provide the name of the healthcare provider we should contact to discuss making arrangements with a certified lab. We will make every reasonable effort to get in touch with the provider you specify.

  Please contact my healthcare provider if results become available in the future ____ (initial)

  Physician Name: _____
  Phone: _____
  Address: _____

- ***Required wording if whole exome or whole genome sequencing studies might or will be done for this research:*** We may (or will) perform a whole genome or whole exome analysis on your sample. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of [*indicate whether the sequencing data will be limited to the disease under study and related disorders or "many diseases or conditions" . Note if your research is subject to the NIH Genomic Data Sharing policy and submitted to dbGaP you must indicate many "diseases*

and conditions" *and cannot limit uses*) it is also possible that this type of testing will discover a gene that you do not know about that may indicate you or a relative is at risk for a genetic disorder in the future.

- ***Required wording for research where tissue/data is sent to NIH (e.g., dbGAP) or other repositories:*** In order to allow researchers to share results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) "banks" that collect the results and analyze data from genetic studies. These central banks may also analyze and store samples and health information form research conducted by Children's Healthcare of Atlanta. These central banks will store your genetic and health information and/or samples and give them to other qualified and approved researchers to do more studies. We do not expect further risks to your privacy and confidentiality by sharing your health information, samples and/or genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your research code number attached. Your name or other directly identifiable information will not be given to these central banks. There are many safeguards in place to protect your privacy.

Who owns my study information and/or samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may still be used for this study.

- *Include an explanation of how you will handle samples if the subject wishes to withdraw from the study, including the ability to request destruction of samples or discontinuation of their use. If samples will be de-identified, explain that once de-identification happens, the samples cannot be re-identified for destruction or discontinuation of use.*

- *Required wording if you request to store remaining samples:* At the completion of this study, we would like to store any remaining samples for possible future use. The remaining samples may be stored indefinitely and may be used for future studies of genetic causes of your disease. The samples will be stored (indicate where). Your sample will be given a unique identification number and stored without your name or other identifiers. Only the investigator will have a list to know which sample is linked to which patient and this list will be kept confidential in a secure location. If the investigator distributes these samples for research into the causes of the disease, it will be released with the unique identifier, but without any names or medical record numbers.

What are the possible benefits of being in this study?

Guidelines:

- *Do not refer to financial compensation or free drugs/treatment in this section.*
- *Any benefits to the subject or other's which may be reasonably expected should be described in a way that is not coercive, enticing or self-serving.*
- *That there may be no direct benefit to the subject. In this case, include the following:* Taking part in this research study may not benefit you personally but we may learn new things that may help others in the future.

What are the alternatives to being in this study?

Guidelines:

- *Describe all procedures or courses of treatment available to the subject outside of this study that might be advantageous to him/her. Generally state the risks and benefits of each alternative, as applicable.*

- *The following is acceptable wording for this section if there are no other alternative treatments or procedures:*

Informed Consent Version:
If the study does not involve treatment, state that: This study does not involve treatment. You will receive similar medical care even if you do not participate.

or

You will receive the same medical care whether or not you participate in the study.

What is the cost of being in this study?

Guidelines:

- *If the subject is likely to incur any costs, this must be stated.*
- *Explain who the costs will be paid by or if there is no cost to the subject for participating. Describe services that the insurance provider may be charged for. Include the following statement, if applicable:* 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 for standard care.
- *State whether the subject will be compensated for their time and travel to participate in the study. Indicate the payment amount, how payment will be issued (i.e., cash, gift cards, etc.), how payment will be prorated and what information you will need to collect for payment (i.e., social security number, address, etc.). If subjects are to be compensated using Clincard the following language should be included:* You will be compensated using "ClinCard", which works like a debit card and is provided by Greenphire. When visits are completed, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. You will have up to XX visits over the period of the study (total that you can receive is $XX). To issue your card, we need to give Greenphire some of your personal information (or your child's). If you do not wish to provide this information, you can still take part in the study, but you will not be paid. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Children's is required by law to report any payments we make to the IRS. To do this, the Finance department needs to keep you social security number on file. We are asking you to allow us to give your name, address, date of birth, research study name and social security number to Greenphire. If you want to receive email or text alerts when payments are made to you, we will ask you to provide your email or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card or use of your personal information. *If payments will exceed $500 in one year, include the following statement:* Since this compensation will be greater than the minimum reporting requirements as set by the Internal Revenue Service (IRS), Children's must report this income to the IRS and will issue you a 1099 form as your compensation will be considered taxable income. We will ask that you provide your social security number for this purpose. You will be responsible for reporting this compensation when you file your tax return.
- *If this is a clinical trial, include the following statement:* This is a Clinical Trial that involves services related to your usual medical care and services related to research. Services related to the research are done only for the purpose of the study; these include: (*insert research services here*). *Clearly indicate whether the research services are provided at no cost to subject or insurance company OR if subject or insurance may be charged for services.*
- *If biospecimens may be used for commercial profit, include the following statement:* Biospecimens may be used for commercial profit and there are no plans for you to share in that profit
-

Commented [C1]: Revise if there are plans for subjects to share in the profit.

What if you are injured while in this study?

For minimal risk studies, include the following statement: "If you think you have been harmed from this study, please call the Principal Investigator at: (insert PI phone number).

For greater than minimal risk studies, include one of the following options that is consistent with your project and any contracts.

Informed Consent Version:
For studies where the sponsor does not pay for subject injury costs or where there is no sponsor: We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children's or Grady Health System or any of the physicians or other personnel involved in individual care or services rendered. No further money has been set aside by Children's Healthcare of Atlanta, Inc. or Grady Health System (or the Sponsor) other than what your insurance carrier may provide. You or your insurance company would be billed for the treatment. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children's or Grady Health System (or Sponsor) employee.

For more information about risks or if you believe you have been injured by this research, you should contact *[insert Principal Investigator]* at *[insert phone number – ensure it directly connects to the PI, or else provide directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours and include a 24 hour emergency contact for interventional studies where subjects may experience adverse events].*

For studies where sponsor may choose to pay for subject injury costs: We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children's or Grady Health System or any of the physicians or other personnel involved in individual care or services rendered.

If you get ill or injured as a direct result of being in this study, the sponsor will pay the costs for your medical treatment if it:

- Is not a medical condition you had before you started the study; is not the result of the natural progress of your disease or condition; is not caused by your failure to follow the study plan; AND is not proven to be directly caused by the negligence of a Children's or Grady Health System or sponsor employee.

You or your insurance company will be billed for any costs of medical treatment for your injury or illness that the sponsor does not pay. No further money has been set aside by Children's Healthcare of Atlanta, Inc. or Grady Health System, other than what your insurance carrier may provide. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children's or Grady Health System or sponsor employee.

For more information about risks or if you believe you have been injured by this research, you should contact *[insert Principal Investigator]* at *[insert phone number – ensure it directly connects to the PI, or else provide directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours].*

For studies where the sponsor may choose to pay for subject injury costs for uninsured subjects or subjects with Medicare/Medicaid and to pay any part of costs for privately insured subjects that are not covered and/or paid by their private insurance: We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children's or Grady Health System or sponsor employee or any of the physicians or other personnel involved in individual care or services rendered.

If you get ill or injured as a direct result of being in this study and you have Medicare, Medicaid or are uninsured, the sponsor will pay the costs for your medical treatment if it:

- Is not a medical condition you had before you started the study; is not the result of the natural progress of your disease or condition; is not caused by your failure to follow the study plan; AND is not proven to be directly caused by the negligence of a Children's or Grady Health System or sponsor employee.

If your case meets the above criteria and you have private insurance, Children's and Grady Health System will review the claims for these costs to see if they can be sent to your insurer for payment. You will have to pay for any costs that the sponsor or your insurer does not pay. The sponsor will pay for any costs that are not paid by your insurance provider. The sponsor will not pay for costs like co-payments that your insurer says you have to pay.

Informed Consent Version:

No further money has been set aside by Children's Healthcare of Atlanta, Inc. or Grady Health System other than what your insurance carrier may provide. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children's or Grady Health System or sponsor employee.

For more information about risks or if you believe you have been injured by this research, you should contact *[insert Principal Investigator]* at *[insert phone number – ensure it directly connects to the PI, or else provide directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours].*

What if there is new information about this study?

Include this section only if subjects will be informed of significant new information found during the course of the study or of changes to the study plan that might affect their decision to participate. This would be applicable, for instance, to a long-term treatment study and not applicable, for instance, to a one-time survey study.

We will tell you about new things during the study that you may need to know or things that might make you want to stop participating in the study.

What if you have any questions or problems while in this study?
If you have any questions, concerns or complaints about this study call [insert Principal Investigator] at [insert phone number]. If you have any questions, concerns or complaints about your rights as a participant in this study, or would like to obtain information, or offer input, you can call the Children's Healthcare of Atlanta Institutional Review Board (IRB) at (404) 785-7477 or via email at irb@choa.org. The IRB is a committee of people that approves all research in this hospital and follows all the rules and regulations made by government agencies about how research is done.

Who will be able to see your records of study participation?

If you are collecting PHI you must include the HIPAA Authorization section of this form. If you are not recording any PHI, describe exactly what information will otherwise be used and how you are going to maintain confidentiality. If you are not accessing PHI, omit this section.

Your records of participation in this study are not accessible to the general public and every effort will be made to maintain confidentiality. However, all records may be subject to subpoena by a court of law. Information that may be gained from this study will be used only for research and educational purposes. Information may be published in medical journals with permission of the Principal Investigator, but your identity will not be revealed or written in a way that you can be recognized. Additionally, identifying information will be available to people from the Children's Healthcare of Atlanta and Grady Health System Human Research Protections Program (i.e., IRB, the Research Compliance Office, Office of Sponsored Programs, Office of Grants Administration, Grants Accounting, the Grady Research Oversight Committee, etc.), the Office for Human Research Protections, the Sponsor(s), and the Food and Drug Administration (FDA), Contract Research Organization (CRO).

- *If the study does not involve medical procedures or tests relevant to the subject's clinical care, include the following required statement:* A copy of this consent form will not be placed in your medical record.

- *If the study involves medical procedures or tests relevant to the subject's clinical care or where the fact of participation is potentially relevant to the subject's clinical care, include the following required statement:* A copy of this consent form will be placed in your medical record. Medical information collected during this study will become part of your hospital record, if the information is determined to be pertinent to your care. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to healthcare professionals at Children's and may be reviewed by Children's staff in their course of

carrying out their responsibilities. Children's staff are required to maintain confidentiality in accordance with applicable laws and Children's policies. Information contained in your medical record may not be given to anyone unaffiliated with Children's in a way that could identify you without written consent, expect as required or permitted by law.

- *If this is a Clinical Trial, please include the following statement:* A description of this clinical trial will be available on 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.

- *If you have a Certificate of Confidentiality, please include the following statement:* We have a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) for this study. The CoC adds special protection for research information that identifies you. The CoC allows Children's to refuse to give out study information that identifies you, even under a court order or subpoena. The CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer or other person obtains your written consent for receive research information, then the researchers may not use the CoC to withhold that information.

  The CoC does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:
  - If the researchers are concerned that you are thinking about killing yourself or are otherwise at immediate risk for seriously harming yourself or others;
  - If researchers learn about serious harm to you or someone else, such as child abuse, steps will be taken to protect you or others;
  - Giving state public health information about certain infectious diseases;
  - Giving study sponsor information about the study, including information for an audit or evaluation.

If you obtained a CoC from a non-NIH agency (i.e., CDC, FDA, HRSA, SAMHSA), use the suggested template language from the agency.

Can I leave the study?

Taking part in this study is completely voluntary. You may choose not to take part in this study. If you take part in this study, you may stop being in the study at any time. Your decision to join or not to join the study will not affect your current or future medical care at Children's.

The study doctor may stop you from taking part in this study for any of the following reasons: you need treatment or medication that may not be taken while on the study or the PI feels it is in your best interest to be taken off this study; you do not follow study procedures or are not able to attend required study visits; withdraw of parent/guardian permission or the study sponsor decides to end the study.

If the study is more than minimal risk, include the consequences of a participant's decision to withdraw from the research. Explain procedures for the orderly termination of participation by the participant.

Contacting Research Subjects for Future Studies

If you are planning to contact these research subjects in the future regarding their potential participation in additional research studies, add the following check box. Please note that if you are planning on creating a subject pool, a separate IRB application should be submitted.

Do you give your permission to be contacted in the future by _____(*insert investigator or staff*) regarding your willingness to participate in future research studies about how to prevent, detect, or treat _____(*insert name of disease)*?

☐ Yes ☐ No _____Initials

Informed Consent Version:

For all studies that include PHI, the following text is required:

Authorization to Release Protected Health Information for Research Purposes

Your health information is protected by a law called the Health Insurance Portability and Accountability Act (HIPAA) is a federal law passed to protect the privacy of your Protected Health Information (PHI). PHI is any information about you that could tell someone who you are. The following information will explain how we will use and disclose your PHI for this study *and any optional studies or substudies in which you may choose to participate.*

Commented [C2]: Omit this text if there are not optional studies or substudies.

What PHI will be collected for this study:

The PHI that we will use or share for the research study includes:

- Medical information about you including your medical history and medications.
- Laboratory test results, results of exams, procedures, interviews and tests you have before and during the study.

Who will collect the information:

The research staff conducting the study will collect and copy your PHI. Your PHI will be used and shared for the conduct and oversight of this study, study related treatment and payment for such treatment. Your PHI will also be used to conduct normal business operations.

Who else will see the information:

- Research staff involved in this study;
- Other staff directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are part of this study, including people who oversee research at those institutions;
- People at Children's and Grady Health System who oversee, advise and evaluate research and care or are involved in the study administration and billing. This includes offices within the Human Research Protections Program (i.e., Institutional Review Board, Research Compliance Office, the Grady Research Oversight Committee);
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information such as data safety and monitoring boards, clinical research organizations, data coordinating centers and others;
- Sponsors or others who fund the research;
- Government agencies that regulate research including the Food and Drug Administration, The Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups hired to provide services related to this research (i.e., service providers, laboratories, etc.);
- Your health insurer for portions of the research and related care that are considered billable
- Greenphire, an independent company specializing in payments for research studies and clinical trials.
- ADD ANY OTHERS, AS APPLICABLE

Commented [C3]: Only include if subjects are compensated.

The Privacy Rule applies to doctors, hospitals, and other healthcare providers. Some of the groups listed above are not required to follow the Privacy Rule and may share your information with others, if other laws allow. However, other privacy protections may still apply. If you have a question about this, you may contact the Children's Privacy Office at 404-785-1516 and they can help you understand privacy and confidentiality.

Identifiers might be removed from identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

Informed Consent Version:
If there is an optional study or substudy, include the same information for that portion below.

How long does the permission last:

Because research is ongoing, this permission will not expire. However, you may cancel this permission at any time.

If you change your mind and want to cancel your permission, you must contact the study team at: (insert study team contact information, including name and address). At that point, researchers would not collect any more PHI, but may use or disclose information already collected for safety reasons, to verify research data or if required by law. If you cancel your permission, you will not be able to stay in the study.

Contact Information

You may use the following contact information to reach the appropriate person/office to address any questions or concerns you may have about this study:

For questions about the study, research-related injuries, emergencies or concerns, contact (Insert PI name and contact number or Insert additional study contact name and number)

If you are a patient receiving care from the Grady Health System and you have questions about your rights, you may contact the Office of Research Administration at research@gmh.edu. Children's Healthcare of Atlanta at Hughes Spalding is owned by the Fulton-DeKalb Hospital Authority (FDHA) and managed by HSOC, Inc., an affiliate of Children's. The FDHA maintains oversight for the Grady Health System.

For questions about your rights as a research participant or if you have questions, concerns or complaints about the research, contact the IRB at 404-785-7477 or irb@choa.org.

Informed Consent and Authorization:
Your signature below indicates that:

- You have read this informed consent form and have been given enough time to consider the decision to participate in the study;
- The research study has been satisfactorily explained to you;
- You have been given the chance to ask questions and have had those questions answered to your satisfaction;
- You understand this study is voluntary and you can withdraw at any time;
- You are signing this consent form prior to participation in any research activities; AND
- You agree to participate in this research study and allow the use of associated protected health information (PHI) as described above.

You will receive a copy of this form.

Informed Consent Version:

Documentation of Informed Consent and HIPAA Authorization

Research Participant:

_____ _____
Printed Name of Research Subject **Date of Birth**
(If the child to be involved in this research study is a foster child or a ward of the state, please notify the researcher or person obtaining your consent)

_____ _____ _____
Signature of Research Subject **Date** **Time**
(*if 18 years or older)*

Parent/Legal Guardian of Research Participant:

Printed Name of Parent/Legal Guardian:_____

_____ _____ _____
Signature of Parent/Legal Guardian **Date** **Time**
(Required for research subjects under the age of 18 years)

Relationship to child: ☐ Parent ☐ Legal Guardian (state relationship):_____

Researcher:

I have fully explained the research study described in this form, including the risks and benefits. I have answered participant and/or parent questions and will continue to answer future questions to the best of my ability. I will tell the participant and/or family if there are changes to the research procedures or risks and benefits that may impact their health or willingness to stay in the study.

Printed Name of Person Obtaining Consent:_____

_____ _____ _____
Signature of Person Obtaining Assent/Consent/Permission **Date** **Time**

Assent Determination:
☐ The child is 5 years of age or younger and assent is not required for participation in this research study.
☐ The child is between the ages of 6-10 years old and has been verbally assented to participate in this research study.
☐ In my opinion, the child is not able to assent to participate in this research study for the following reason:

Interpreter:

_____ _____ _____
Signature of Interpreter (if applicable) **Date** **Time**