Informed Consent Form

TITLE: Sickle Cell Disease Treatment With Arginine Therapy (STArT) Trial

NCT NUMBER: NCT04839354

IRB APPROVAL DATE: March 21, 2022

Consent/Parental Permission Authorization Document

Emory University/ Children's Healthcare of Atlanta

Study Title: **Sickle Cell Disease Treatment with Arginine Therapy (STArT) Trial**

Principal Investigator: **Dr. Claudia R. Morris, MD, FAAP**

Source Sponsor: **National Heart, Lung, and Blood Institute (NHLBI)**

Multicenter: **Pediatric Emergency Care Applied Research Network (PECARN)**

If you are the parent or legal guardian of a minor child who is being asked to participate, the term "you" used in this consent refers to your child.

This form is called a consent and authorization form; it explains:
- The reason for this study.
- What will happen during this study.
- The risks to you being in this study.
- The benefits, if any, of being in this study.
- Questions you may have.

Before you decide if taking part is right for you, it is important that you read this form and understand the study. If there is anything you do not understand about the study, please ask your study doctor or any study team member.

STUDY SUMMARY

This part of the consent is a short description of this study. More complete details are described after this summary.

You are free to choose if you want to be in this study or not. It is your choice. No matter what you decide, you will still be able to receive medical care from your doctor.

Arginine is a protein in your body. Arginine is also an essential nutrient found in many foods. People with Sickle Cell Disease (SCD) have low levels of arginine. These low levels may be why people with SCD have pain. This study is being done to find out if adding arginine therapy will help shorten sickle cell pain episodes.

About 360 patients will be in this study.

You will be given up to 21 doses of study drug (this takes 7-8 days) or until you leave the hospital, whichever comes first. You will not have any extra visits after you leave the hospital. However, the study team will look at your medical record for 28 days after you leave the hospital to see if you returned to the hospital.

You will be screened to find out if you can be in the study. There will be a review of your medical record. Blood will be drawn from you, and some blood tests will be done.

If you pass the screening tests, you will be assigned to receive one of two study treatments, either arginine or placebo. A placebo is an inactive substance. In this case, a saltwater solution. They will both be given through an IV, intravenous, or through the vein, regardless of what group you are in. The study procedures will be explained in detail later in this document.

There are known side-effects that may occur as a result of the study drug used in this study. The study team does not know all the side-effects that the study drug may have on you. These effects may be mild or serious. There is also the risk of an allergic reaction to the drug. The risks are explained in more detail later in this document.

There are no direct benefits to you from taking part in this study. The information we get from this study may help us treat future patients. We hope that this study will help you. However, this cannot be guaranteed.

BACKGROUND

Why is this research being done?

This study is being done to find out if IV arginine, given with pain medicine, will shorten how long the pain lasts. We believe adding IV arginine may help with the pain than just pain medication alone.

Arginine given by IV has not been approved by the Food and Drug Administration (FDA) to treat sickle cell pain.

Studies have shown that arginine IV in the arm is safe. Unfortunately, we still do not know if it will help with pain episodes.

No one knows why a sickle cell-related pain episode starts. We do know once the pain starts that there are no therapies that treat the underlying cause for the pain. Treatment for sickle cell pain episodes has not changed much over the last 30 years. The usual treatment includes IV fluids and pain medicines (drugs like morphine, codeine, Tylenol, or ketorolac). Intranasal (putting the medicine up your nose) or IV pain medicine are often required. Therefore, we need to find more medicines that can help treat sickle cell-related pain.

This study is being done at 10 different places across the United States and is being led by Dr. Claudia Morris. You have a right to know about what will happen to you, the possible risks and benefits of this study to help decide if you want to be in this study.

Who is being asked to take part in this research study?

Anyone who is 3-21 years of age having sickle cell pain and not getting better with pain medicine may be asked to be in this study.

How long will the study last?

The study will last from the time you sign consent until the time you leave the hospital. You will be given up to 21 doses of study drug (this takes 7-8 days) or until you leave the hospital, whichever comes first. The study team will review your medical record for 28 days after you leave the hospital.

STUDY PROCEDURES

What procedures will be performed for research purposes?

If you agree to be in this study, the following will occur while you are in the hospital:

Randomization/Study drug - You will be “randomized” into one of the study groups described below (Arginine group or Placebo group). Randomized means that you will be put into a group by chance. It is like flipping a coin. The group you will be put into is decided by a computer. Neither you nor your doctor will know which group you are in (although, if your doctor needs to find out for important medical reasons, he/she can do so). You will have an equal chance of being placed in either group. Using randomization helps to improve the chance of finding out if arginine helps reduce sickle cell related pain.

- **Arginine group:** The study drug will be given by IV.
- **Placebo group:** The study drug in this group will be a placebo, which is harmless saltwater that contains no active drug. It is used as a comparison to see if the study drug works differently than the placebo.

You will still get your normal standard of care pain medicine no matter what group you are in.

Questionnaires – You will be asked a list of questions asking about how you are doing and how you are functioning. The first time these will be given will be around the time you receive the first dose of your study drug and every day until you get your 21st dose or until you leave the hospital. As part of these questions, we will ask how your pain has changed since your pain started. It will take about 20 minutes to answer all the questions.

Tests -

- Complete Metabolic Panel (blood test) if it hasn’t been done as part of your standard of care. This is a blood draw.
- A pregnancy test (if you have had your first period).
- 3 extra blood draws for research (about 2 tablespoons of blood each):
    1. before you get the first dose of study drug.
    2. day 2 of being in the study.
    3. when you leave the hospital or when you get your last dose of study drug. If you stay in the hospital after you receive your last dose, blood for research will be collected on the day of your last dose and on the day you leave the hospital.

It is possible you could get up to 6 blood draws. These include up to 3 blood draws for the complete metabolic panel (this testing could be done up to 3 times depending on results) and up to 3 extra blood draws for research.

The reason for these research blood draws is to see how the study drug is changing the pain in your body and to make sure that you are not having problems from the study drug. This blood will help to better know how arginine levels in blood change during times of pain. It will also allow us to look at how arginine treatment changes the amount of arginine in your blood and also how arginine helps cells function. Genetic testing will not be done as part of this study. These research blood draws will not be used for any testing outside of standard care or beyond the scope of this study unless you allow us to use your blood for future research (see below: Blood Biorepository).

You will not receive the results of the research blood draws.

<u>Blood Biorepository (optional)</u> – if you agree, we would like to put some of your blood in a “blood biorepository” so that researchers can use it in the future. A biorepository stores blood for research that might be done in the future by us or other researchers, but we don’t know what that research will be. For this biorepository, the future research will only be about SCD. This future research may help us learn more about the disease and ways to treat it. You will not get the results from any future research.

Genetic testing will not be done on any of your blood in the biorepository. Your blood will be kept in a secure location at Emory University. It will be kept for about 10 years or longer depending on how long the biorepository is needed and has money available to keep it running.

Your sample will have a code on it so that your name is not on the sample. This means that Dr. Claudia Morris and Emory University will keep your name in a separate place from your sample so that we can link your sample back to you later if we need to. Once the additional research for this study has been completed, the information that identifies you and links you back to your sample will be removed.

Your sample may be shared with researchers at Emory University and at other hospitals/universities for SCD research only. These researchers will have to be approved by Dr. Claudia Morris to use your samples. Dr. Claudia Morris will be in charge of keeping records of your samples and/or data that is released for future research, as well as when and to whom the samples are released.
Also, Dr. Claudia Morris will not give your name to other researchers who want to use your sample but will only give them information like your age and what disease you have. You may be contacted in the future if other researchers want to use your samples for other kinds of testing on Sickle Cell Disease.

If you no longer want your blood sample to be used for future research, you can have your blood sample taken out of the biorepository and destroyed at any time. To have your sample taken out of the biorepository, all you need to do is call Dr. Claudia R. Morris, MD, FAAP at [redacted] Please know that if you ask for your blood sample to be taken out of the biorepository, it cannot be taken out from other hospitals/universities if it has already been shared. However, other researchers will not know whose blood they are studying, as no information that identifies you will be shared.

You do **not** have to participate in the biorepository to be in the main part of this study. No matter what you decide to do, your decision will not affect your medical care. You can tell us your choice by initialing at the end of this form.

Tissue or blood samples taken from you in this research may help in the development of a commercial product by Emory University or its research partners. You will not be provided money should this occur.

POSSIBLE RISKS AND DISCOMFORTS

What are the possible risks, side effects, and discomforts of this research study?

While in the study, you are at risk for the below side effects. You should discuss these with the researcher and/or your sickle cell doctor.

1. Drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely, infection. Research blood draws will be timed with clinical blood draws whenever possible to minimize discomfort.

2. You may feel a warming sensation when the study drug is given.

3. Arginine risks:
    a. As with any food or medicine, the risk of an allergic reaction is a small but a possible problem. An allergic reaction is a response to medication or food that causes mild to severe symptoms. Mild symptoms include hives, itching, nasal congestion, rash, scratchy throat, and watery or itchy eyes. Severe symptoms include swelling of the airway, inability to breathe, and a sudden drop in blood pressure.

    b. Side effects of arginine in this study may include:
        - Flushing.
        - Headache.
        - Nausea or vomiting.

    c. Rare, more serious side effects include:
        - Acidosis (too much acid in the body fluids).
        - Hyperkalemia (higher than normal potassium in your blood)
        - Death has been reported in a patient with severe kidney failure as a result of an overdose. Participants with a history of significant kidney disease or are found to have significant kidney disease will be removed from the study if a blood test shows significant kidney problems. Your blood will be checked as part of this study before you get study drug to check your kidney function. The study drug will be handled by a licensed pharmacist to make sure you get the proper dose.

4. The questionnaires will take about 15-20 minutes for you to complete. Some of the questions being asked may make you feel uncomfortable. You do not have to answer these questions, and we can help you in finding support if you feel any pain related to this.

5. Loss of privacy is a risk when being in a study, but protections are in place to guard against this. Loss of privacy means that someone who gets access to your personal medical information shouldn't have access to it.

6. Reproductive Risks – Effects of arginine given to a pregnant woman on the unborn baby are unknown. Pregnant women must not take part in this study. Women who are able to get pregnant will be asked to have a pregnancy test before taking part to make sure they are not pregnant.

7. Unknown Risks - In addition to the risks listed above, you may have an unknown risk or side effect occur**.**

DESCRIPTION OF BENEFITS

What are the possible benefits of taking part in this study?

There are possibly no direct benefits to you from taking part in this study. We hope that you may have less pain and a shorter hospital stay, but this is not certain. If the study drug works as hoped, the information that we get may help others with SCD as well. Also, the results from the blood draws will teach us more about what happens during a sickle cell pain crisis, which could lead to better treatments in the future.

ALTERNATIVE PROCEDURES

What treatments or procedures are available if I decide not to take part in this research study?

If you do not want to be in the study, you may choose not to take part, and your other treatment will not be affected. You will continue to receive standard therapy for pain as well as other supportive care measures. Please talk to your sickle cell doctor about these and other options.

VOLUNTARY PARTICIPATION

Is my participation in this research study voluntary?

If you decide to take part in this study, you are still free to remove yourself at any time and without giving a reason. No one will get angry or upset if you do not want to be in the study. You will not be punished or lose any benefits. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor lessen the standard of care that you receive as a patient.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your study doctor or another doctor/researcher can remove you even if you don't want to be removed. The best medical care is the main concern of your doctor and the researcher. If your doctor decides that taking part in this study will get in the way of you getting the best care, then he/she can take you out of the study.

COSTS TO SUBJECTS AND COMPENSATION

Will my insurance or I be charged for the costs of any services done as part of this study? You and your insurance will not be charged for taking part in this study. However, you will be responsible for the costs of routine services and your hospital stay, no matter if you are in the study or not.

The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory, Grady Health System and Children's Healthcare of Atlanta will submit claims to your insurance for items and services that the sponsor does not cover. Emory, Grady Health System and Children's Healthcare of Atlanta will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid. The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory, Grady Health System, and Children's Healthcare of Atlanta and the sponsor will not pay for these costs. It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory, Grady Health System and Children's Healthcare of Atlanta will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Will I be paid if my child takes part in this research study?

You will be paid $100 for you completing the study. You will receive a $50-dollar gift card after you receive the study drug and another $50-dollar gift card after research labs are collected when you leave the hospital or on the day you receive your 21st dose.

COMPENSATION IF INJURY OCCURS

Who will pay if I am injured as a result of taking part in this study?

If you believe you have become ill or injured from this research, you should contact the study doctor at the telephone number listed on the first page of this form. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory, Grady Health System and Children's Healthcare of Atlanta will help you get medical treatment. Neither Emory, Grady Health System and Children's Healthcare of Atlanta nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory, Grady Health System, and Children's Healthcare of Atlanta and the sponsor have not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. "Negligence" is the failure to follow a standard duty of care.

CONFIDENTIALITY

We will keep all research records that identify you private, to the extent allowed by law. Staff from this hospital/university, the network leading the study, and others working with us may review your medical records for this study. Other federal agencies that oversee research activities (for example, the Office for Human Research Protections (OHRP) or the Food and Drug Administration (FDA), etc.) may review your records. All information collected about you during the study will be kept private. Results of the study may be printed, but your name and all other information that would identify you will be kept private. Any information about you that leaves the hospital will have all names, and medical record numbers removed so that you cannot be known.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory, Grady Health System, Children's Healthcare of Atlanta will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory, Grady Health System, or Children's Healthcare of Atlanta received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory, Grady Health System, and Children's Healthcare of Atlanta from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

PERSON TO CONTACT

If you have any questions about this study (including information about treatment and payment), or if you have any side effects or injury while you are in this study, you should call Dr. Claudia R. Morris, MD, FAAP at [redacted].

We will give you emergency care if you are injured by this research. However, **Grady Health System** has not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Claudia R. Morris, MD, FAAP Phone: [redacted]

INSTITUTIONAL REVIEW BOARD

If you have questions about your rights as a study subject, or if problems come up that you do not feel you can tell your study doctor, please call the Institutional Review Board Office at 404-712-0720 or 877-503-9797 or irb@emory.edu

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

If you are patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu

NEW INFORMATION

A Data Safety and Monitoring Board, a separate group of experts, will be reviewing the data from this research throughout the study and reporting back to the research team. We will tell you about the new information from this or other studies that may affect your health, safety, or willingness to stay in this study.

NUMBER OF SUBJECTS

We plan to study about 360 people age 3-21 years old who are having an acute pain episode in a multi-center trial (meaning that the research will be done at our hospital and as many as 10 or more other children’s hospitals around the US) to see if it shortens the hospital stay. About 36 people will be recruited from our hospital. Patient enrollment is anticipated to be completed within 60 months.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this study. You can choose whether or not you will participate in this study. However, in order to take part in this study you have to sign this consent and authorization form.

The privacy of your health information is important to us. We call your health information that identifies you, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:

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

- Date of joining the study.
- Your date of birth.
- Information such as race, ethnicity and sex.
- Results from tests / procedures that are part of regular care and may be done even if you do not join the study: vital signs, medical history, physical exam, blood draws to evaluate your red blood cell count.

- Results of the following tests will also be collected: CBC, reticulocyte count, electrolytes, BUN, creatinine, hemoglobin, hematocrit, WBC count, platelet count, plasma nitrite, serum magnesium and calcium, serum sodium, potassium, chloride, bicarbonate, and LDH, any x-rays or radiologic studies ordered by the clinical team including chest radiographs, abdominal ultrasounds etc.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory, Grady Health System and Children's Healthcare of Atlanta may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- NHLBI is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Staff of the federal agencies that fund the research network.
- The University of Utah Institutional Review Board (group of people that make sure studies are safe).

- Approved members of the University and hospital who need the information to do their duties (for example: to provide care, to make sure the research is honest, and for accounting or billing matters).

The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.

- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory, Grady Health System and Children's Healthcare of Atlanta offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory and CHOA IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration.
    - The IRB of Record
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Storage of [Data and/or Specimens] for Future Research:

PHI That Will be Used/Disclosed for Storage of [Data and/or Specimens] for Future Research:
The PHI that we will use and/or disclose (share) for the optional research study any samples collected for this purpose as mentioned in this form, age and disease along with other information. Your name will not be mentioned

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the optional research study, including the administration and payment of any costs relating to subject injury.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Storage of [Data and/or Specimens] for Future Research:

The following people and groups will use and disclose your PHI in connection with the optional research study:
The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional research study/storage of PHI for future research

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.
We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.
An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

You may also contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Your information will be kept safe and your records will be password protected. Your information may be kept with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular care, payment, and health care services of the hospital. We may also need to release information if required by law.

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

- The University of Utah Data Coordinating Center protects the privacy, truth, and access of your personal information. Your personal information will only be used and given to approved people who help us manage or deliver services during the study. Your personal information will not be shared, sold, used or given out for any other purpose. Your information will be kept for as long as is needed to provide the described activities and to follow study related laws.
    - You have the right to get, correct, change, or remove your information at any time by calling the study staff. If you are removed from the study, the study staff will stop giving your personal information to the University of Utah Data Coordinating Center. However, information already given before consent was removed will not be removed.

- In order to conduct this study and make sure it is done as told in this form, your research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team, Emory University and the University of Utah;
    - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
    - The study sponsor NIH and its representatives;
    - Contractors or consultants working for the sponsor.

- If we share your personal information with groups outside of Emory, Grady Health System and Children's Healthcare of Atlanta they may not have to follow the same federal privacy laws that we follow. They may also share your information with others not described in this form.

- If you do not want us to use information about your health, you should not agree to allow you to be part of this research. If you choose not to allow you to participate, you can still get health care services at Emory, Grady Health System and Children's Healthcare of Atlanta

What if I decide to Not Be in the Study after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want you to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be removed from the study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date. You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT/PARENTAL PERMISSION

I agree that I have read and understand the consent/parental permission and authorization document for the above study and have had the chance to ask questions. I understand that me being in the study is my choice and that I am free to stop at any time, without giving any reason, without my medical care or legal rights being changed. I know that my medical notes may be looked at by approved people from the study network or from regulatory authorities. I allow these approved people to have access to my records. I will be given a signed copy of this form to keep or a copy of signed form will be emailed to me. **I agree to take part in this study and allow you to use and release my health information for this study, as you have explained in this form.**

____
Your Name

___________________________________ ______________________
Your Signature (**18 years and older only**) Date and time

Signature of the parent/legal guardian provides consent for the subject to participate in the study for subjects 17 years old or younger.

____
Parent/Guardian’s Name

____
Parent/Guardian’s Signature

___________________________________ ______________________
Relationship to Child for Parent/Guardian Date and time

Biorepository Consent (optional)

______ **YES**, my sample(s) may be saved for future Sickle Cell Disease research.
(initial)

______ **NO**, my sample(s) must be destroyed at the end of this research project.
(initial)

____
Name of Person Obtaining Authorization and Consent

____________________________________ ________________________
Signature of Person Obtaining Authorization and Consent Date and time