

## Informed Consent to Participate in Research



Your Name: \_\_\_\_\_

**Study Title:** **Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease**

**Protocol:** BMT CTN # 1507

**Principal Investigator:** [Insert site PI]

**Co-Investigators:** [Insert site co-I]

**Study Coordinators:** [Insert site study coordinator/s]

[Insert site department/facility name, address, and phone number]

**Sponsor:** National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (the NIH), Bethesda, Maryland

**CONSENT FOR AN ADULT OR CHILD TO BE A SUBJECT IN CLINICAL RESEARCH AND AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES.**

## 1. Introduction

We invite you to join this clinical trial. A clinical trial is a research study. You're being asked to join this study because:

- You have **Severe Sickle Cell Disease (SCD)**
- You're between 5 - 45 years old
- An **allogeneic transplant** is a treatment option for you
- You have a donor (parent, brother, sister, or other family member) who is a half match

SCD is sometimes treated with an allogeneic transplant (also known as a bone marrow transplant). An allogeneic transplant may use a matched or mismatched donor.

We're doing this study to learn if a new type of allogeneic transplant called a **haploidentical transplant** is safe and effective to treat SCD. This study will use a parent, brother, sister or other family member who is a mismatched donor that has a half match with you.

If you agree to be in the study it will be for 2 years. The study will include 80 people (40 children and 40 young adults) at 30 – 40 transplant centers.

Definitions of **bolded terms** are in the next section.

This Consent Form will tell you about the purpose of the study, possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take your time to make your decision.

Everyone who takes part in research at **[insert facility name]** should know that:

- Being in any research study is voluntary.
- You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others.
- If you join the study, you can quit the study at any time.
- If you decide to quit the study, it will not affect your care at **[insert name of facility or institution]**.
- Please ask the study staff questions about anything that you do not understand, or if you would like to have more information.

- You can ask questions now or any time during the study.
- Please take the time you need to talk about the study with your doctor, study staff, and your family and friends. It's your decision to be in the study. If you decide to join, please sign and date the end of this Consent Form.

You and your doctor will discuss other treatment choices if you don't want to participate in this study.

## 2. Study Background

The National Institutes of Health (NIH), through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), are providing staff support and money for this research study. The BMT CTN and the NIH will make decisions about how to manage the study.

### Severe Sickle Cell Disease and Allogeneic Transplant

**Severe Sickle Cell Disease (SCD)** is a blood disorder you're born with. Red blood cells carry oxygen to different parts of your body. SCD is caused by a change in **hemoglobin**, the protein that helps red blood cells carry oxygen in the body. The change blocks the blood flow in small vessels which can cause severe (serious) pain. It can also damage your lungs, brain, kidneys, and other organs. A person with SCD lives about 30 years shorter than a person without SCD.

An **allogeneic transplant**, or bone marrow transplant, uses healthy blood-making cells from a donor to replace unhealthy ones. It requires donors and patients to have matched **human leukocyte antigens (HLA)**. HLA is a protein marker found on most cells in your body. HLA markers are inherited (given to you from your mother or father). You get half of your HLA markers from your mother and half from your father.

A **haploidentical transplant** is an allogeneic transplant where the donor matches exactly half of your HLA. Parents are always a half-match for their biological children and children are always a half-match for their biological parents. Biological siblings (brothers or sisters) have a 50% (1 out of 2) chance of being a half-match for each other.

In this study, we want to learn if a **haploidentical transplant** is effective and safe to treat SCD. This study will use a parent or other half-matched family member donor. This treatment may stop the disease and many of its health problems. But there is also a chance that it may not work and the disease can come back.

### Allogeneic Transplant – Reduced Intensity Transplant

There are 2 main steps with allogeneic transplant. First, to prepare your body, we use chemotherapy and radiation to destroy the abnormal blood cells. This step is called the

**conditioning regimen.** Then, when the conditioning regimen is done, you're given the donor cells for your transplant.

In this study, your doctor will use lower doses of chemotherapy and radiation than are normally used for allogeneic transplant. This is called a **reduced intensity transplant.**

### 3. Study Purpose

We're doing this study to learn if a **haploidentical transplant** is safe and effective to treat SCD. A haploidentical transplant uses a half or partially-matched donor. ("Haplo" means half.) This study will use a parent or other family member who is a half tissue match.

You're being asked to join this study because you:

- Are between 5 – 14 years old and had a stroke.
- Are between 15 – 45 years old and had 1 or more of the following:
  - Stroke
  - 2 or more episodes of acute chest syndrome in the last 2 years while getting other treatment such as hydroxyurea
  - 3 or more episodes of serious pain crises in the last 2 years while getting other treatment such as hydroxyurea
  - Regular red blood cell (RBC) transfusions (8 or more transfusions during the last year to prevent sickle-related health problems)
  - Fast blood flow in your heart and in the wrong direction. This may mean you may have a higher risk of dying.
- Have a donor (parent, brother, sister, or other family member) who is a half match

You can't be in this study if you have one or more of the following:

- A brother or sister who closely matches more than half of your HLA
- Liver cirrhosis (damage to the liver which can lead to scarring and liver failure)
- A very serious bacterial, fungal, or viral infection in the past 6 weeks
- HIV infection

- Already had a bone marrow transplant
- Joined a study where you took a study drug or used a medical device.
- A serious autoimmune disorder (where your own immune system attacks your body) like lupus or scleroderma
- Are currently pregnant or breast feeding
- Do not agree to use contraception or sexual abstinence for 12 months after the bone marrow transplant

#### **4. Right to Ask Questions and/or Withdraw**

You have the right to ask questions about the study at any time. If you have questions about your rights as a participant or you want to leave the study, please contact:

[Insert contact info]

Being in this study is voluntary. You can choose to not be in this study, or leave this study at any time.

If you choose not to take part or to leave this study, it will not affect your regular medical care in any way.

Your study doctor and study staff will be available to answer any questions that you may have about taking part or leaving this study.

#### **5. Study Treatments and Tests**

If you join this study, we'll check your health before, during, and for 2 years after your treatment.

##### **Before Your Treatment**

You'll have several check-ups and tests before your transplant. Some of these tests are given to all patients who get a transplant. Others are for this study only.

Some of the tests will be done up to 6 months before you enroll and some of the tests will be done later, about a month before enrolling on the study and then again before starting the drug called hydroxyurea, or before starting the drug called ATG (Thymoglobulin). The tests that are given to all transplant patients (not just patients in this study) and include:

- Medical history, including past and present use of medications. **Note:** Incomplete information could have a serious effect on your health and safety.
- Physical exam, height and weight
- Performance score to see how well you can do certain activities like going to work and caring for yourself
- Urine test to check for proteins and infections
- Radiology test or a 24-hour urine collection to learn how well your kidneys work
- 1 tablespoon of blood to check for:
  - Blood counts including the number of platelets
  - Number of elements and minerals in your blood
  - Different kinds of hemoglobin proteins in your red blood cells
  - Infections with hepatitis, herpes simplex, syphilis, HIV, Human T-Lymphotropic Virus (HTL), chicken pox, and shingles that are active now or happened in the past
- 1 teaspoon of blood for:
  - Pregnancy test, if you're female and able to get pregnant

The total amount of blood needed for these tests will be a little over 3 teaspoons.

- Optional research samples
  - If you agree, we will also collect about 4-8 teaspoons of blood for research.

Other tests for this study include:

- Pain diary: Your doctor and/or research team will provide the instructions you will need to complete the pain diary. If you speak English and are 15 or older, self-documentation of pain will occur twice daily for 28 days via an electronic application.
- Questions about your health and quality of life if you speak English or Spanish and are 15 years or older (to find out how healthy you feel you are and how well you can do your everyday activities): a survey to measure health outcomes from the patient perspective. Your doctor and/or the research team will provide the instructions and materials you will need to complete the survey at each time point it is due.

- Electrocardiogram (ECG and EKG) to take pictures of your heart and see how well it's working
- Chest X-ray
- Lung function tests to see how well your lungs work (including a test to see how far you can walk in 6 minutes)
- Brain scan (MRA or MRI) to show a picture of your brain and its blood vessels
- MRI of your liver if you've had a lot of red blood cell transfusions
- Liver biopsy if needed (we'll take a small sample of your liver if your liver MRI shows high iron) to see if there is damage from iron
- Cardiac scan (MRI) if needed
- HLA typing and blood test for rejecting the donor bone marrow
- Data regarding your clinical situation, including follow-up 2 years after your transplant, may be obtained from the CIBMTR, which captures information on all US transplants.

## **During Your Treatment**

### Getting Your Catheter:

A surgeon will place a **central venous catheter** in your body, most likely in your chest. A catheter is a thin, hollow tube that allows medicines, blood transfusions, and blood draws to be done painlessly and to avoid repeated needle sticks. It's also called the "central line".

The catheter will need to be cleaned every day to avoid blood clots and infection. You and your caregiver will be given instructions on how to take care of the catheter.

The surgeon will talk with you before the surgery about the risks related to having a catheter.

### Preparing for Transplant:

To prepare your body for transplant, we use chemotherapy and radiation to destroy or stop the abnormal blood cells from being made. This step is called the "conditioning regimen".

The chemotherapy (chemo) drugs also help the donor cells engraft. "Engraft" means that the cells start to grow and make new cells, and show up in your blood.

See **Table 1: Schedule of Treatments Before and After Transplant** for a list of the chemo drugs you'll get and how often you'll take them. The chemo drugs and radiation before transplant include:

1. Hydroxyurea: This treatment will start in the hospital (or clinic) and continue at home.
2. Rabbit anti-thymoglobulin (rATG)
3. Thiotepa
4. Fludarabine
5. Cyclophosphamide
6. Total body irradiation (TBI): A single dose will be given while you are put in front of a machine.

Transplant Day:

On transplant day (Day 0), you'll get your donor cells through your catheter. Your blood pressure, heart and respiration rates, and temperature will be taken before and during the transplant.

The study doctor may also give you medicines before the transplant to help with any side effects or discomfort. Some of these side effects and discomforts include:

- Complications with catheter like blood clots and infection
- Slow recovery of blood counts
- New stem cells aren't growing at all (graft failure) which means you continue to have your disease
- **Graft-Versus-Host Disease (GVHD)** (described below)
- Damage to the vital organs in your body
- Serious infections
- Disease comes back (this happens when your body rejects the new stem cells)
- Death
- Reproductive risks (ability to have or father children after the transplant)

See Section 6: Risks and Discomforts for more information.

## **After Your Transplant**

### Graft Versus Host Disease (GVHD) Prevention Drugs:

**Graft Versus Host Disease (GVHD)** happens when the donor cells see your body as foreign (or different) and attack it. It can be a very serious side effect of transplant.

We'll give you 3 drugs to help prevent GVHD after your transplant. See **Table 1: Schedule of Treatments Before and After Transplant** for a list of the GVHD prevention drugs you'll get and how often you'll take them:

1. Cyclophosphamide: You'll get cyclophosphamide to prevent GVHD and also to help the donor cells engraft. "Engraft" means that the cells start to grow and make new cells and show up in your blood.
2. MESNA: Because there is a risk of irritation and damage to the bladder, MESNA will be given before and after cyclophosphamide to help protect the bladder.
3. Mycophenolate mofetil (MMF): Your doctor may keep giving MMF to you after 35 days, if you have GVHD.
4. Sirolimus: The study doctor may change the dose based on how your body reacts to the drug. Also, your doctor may keep giving it to you after 1 year, if you have GVHD.

**Table 1: Schedule of Treatments Before and After Transplant**

Treatments	Days -70 to -10	Days -9, -8	Da y -7	Days -6, -5	Days -4 to - 2	Da y -1	Day 0 (Transplan t day)	Days +3, +4	Days +5 to +35	Days +5 to +365 / 1 year
Hydroxyurea, by mouth	X									
Rabbit anti-thymocyte globulin (rATG), by IV		X	X							
Thiotepa, by IV 2 times in one day			X							
Cyclophosphamide, by IV 2 times daily				X						
Fludarabine, by IV				X	X					
Total body irradiation (TBI), 1 dose standing in front of machine						X				
Transplant day (donor marrow)							X			
Cyclophosphamide, by IV								X		
Mesna, by IV before and after cyclophosphamide								X		
Mycophenolate mofetil (MMF), by mouth or injection 3 times daily									X	
Sirolimus, by mouth										X

After-Transplant Tests:

1 to 100 days after your transplant (Day 1 – 100)

- Weekly GVHD tests
- Weekly Medical history, physical exam, height and weight (until Day 28)
- Weekly Performance score to see how well you can do certain activities like going to work and caring for yourself (until Day 28)
- 1 Tablespoon of blood to check for:
  - Blood counts including the number of platelets (two times per week until Day 28, weekly until Day 84)
  - Number of elements and minerals in your blood (beginning on Day 28 until Day 100)

28 days after your transplant (Day 28)

- Blood or bone marrow sample to find the amount of donor cells in your body (chimerism test) done at Day 28 and Day 42 (if needed)
- Weekly Medical history, physical exam, height and weight
- Optional blood samples

60 days after your transplant (Day 60)

- Optional blood samples

100 days after your transplant (Day 100)

- Medical history, physical exam, height and weight
- Hemoglobin (blood) test to measure how much sickle hemoglobin is in your blood
- Performance score to see how well you can do certain activities like going to work and caring for yourself
- Blood or bone marrow sample to find the amount of donor cells in your body (chimerism test)
- Optional blood samples

6 months after your transplant (Day 180)

- Performance score to see how well you can do certain activities like going to work and caring for yourself
- Hemoglobin (blood) test to measure how much sickle hemoglobin is in your blood
- GVHD tests
- Blood sample to find the amount of donor cells in your body (chimerism test)
- Blood counts including the number of platelets
- Weekly Medical history, physical exam, height and weight
- Optional blood samples

18 months after your transplant (Day 540)

- GVHD tests

1 and 2 year(s) after your transplant (Day 365 and Day 730)

- Medical history and physical exam, including height and weight
- GVHD tests
- Immune system test to see how well your immune system is working
- Hemoglobin (blood) test to measure how much sickle hemoglobin is in your blood
- Blood counts including the number of platelets
- 24-hour urine collection to learn how well your kidneys work
- Lung function test and oxygen level
- 6 minute walk distance test
- Echocardiogram (echo) to take pictures of your heart and see how well it's working if your doctor determines this is needed
- Cardiac MRI if needed

- Liver MRI for those with iron overload
- Brain scan to show a picture of your brain and its blood vessels
- Questions about your health and quality of life if you speak English or Spanish and are 15 or older
- Blood sample to find the amount of donor cells in your body (chimerism test)
- Twice daily pain diaries if you are 15 or older (Days 337-365 and Days 702-730)
- Optional blood samples (at Day 365)

Most of these tests will be done as part of your regular medical care after transplant. The tests for this study include: lung function test, echocardiogram (if needed), questions about your health and quality of life, brain scan, and optional blood samples.

**Table 2: Timeline of Tests after Your Transplant** lists the tests you’ll have after your bone marrow transplant.

**Table 2: Timeline of Tests after Your Transplant**

Tests	Days <u>After</u> Transplant							
	Day 1- 100 (weekly)	+42	+60	+100	+180	+365	+540	+730
Tests for GVHD	✓				✓	✓	✓	✓
Test required by the hospital, including blood and urine tests	✓	✓		✓	✓	✓		✓
Hemoglobin (blood) test				✓	✓	✓		✓
Tests to see how much of the donor cells are in your body (chimerism)	✓ (Day 28)	✓ (if needed)		✓	✓	✓		✓
Quality of life surveys if you speak English or Spanish and are 15 or older						✓		✓
Performance score to see how well you can do certain activities like going to work and caring for yourself	✓ (weekly until Day 28)			✓	✓	✓		✓
Immune system test						✓		✓

Tests	Days <u>After</u> Transplant							
	Day 1- 100 (weekly)	+42	+60	+100	+180	+365	+540	+730
Lung function test (including a test to see how far you can walk in 6 minutes)						✓		✓
Echocardiography test to take pictures of your heart and see how well it's working (if needed)						✓		✓
Brain scan						✓		✓
Pain diaries over 28 days if you speak English and are 15 or older						✓		✓
Cardiac MRI (if needed)						✓		✓
Liver MRI (for those with iron overload)						✓		✓
Optional blood samples	✓ (Day 28)		✓	✓	✓	✓		

## 6. Risks and Discomforts

You may have side effects while on the study. Side effects can range from mild to serious. Your health care team may give you medicines to help with certain side effects like nausea (feeling sick to your stomach). In some cases, side effects can last a long time or may never go away.

### Risks of Medicines

**Table 3: Risks and Side Effects** shows how side effects are grouped together. The 3 groups are based on how often patients get each side effect.

**Table 3: Risks and Side Effects**

<b>Likely</b>	What it means: This type of side effect is expected in <u>more than 20% of patients</u> . This means that 21 or more patients out of 100 might get this side effect.
<b>Less Likely</b>	What it means: This type of side effect is expected in <u>20% of patients or fewer</u> . This means that 20 patients or fewer out of 100 might get this side effect.
<b>Rare, but Serious</b>	What it means: This type of side effect is expected in <u>fewer than 2% of patients</u> . This means that 1 or 2 patients (or fewer) out of 100 might get this side effect. It doesn't happen very often, but is serious when it does.

### Risks of Conditioning Regimen Medicines

The risks of the chemotherapy drugs you get as part of the conditioning regimen are listed below.

**Hydroxyurea – Chemotherapy drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up</li> <li>• Diarrhea</li> <li>• Loss of appetite</li> <li>• Low number of red blood cells (anemia)</li> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Mouth sores</li> <li>• Throat inflammation (sore, red, swollen throat), going down to the stomach</li> <li>• Bleeding</li> <li>• Infection</li> </ul>	<ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Headaches</li> <li>• Changes in behavior</li> <li>• Confusion</li> <li>• Seeing or hearing things that are not really there</li> <li>• Feeling drowsy</li> <li>• Abnormal liver tests</li> <li>• Yellow tint to skin or eyes (jaundice)</li> <li>• Darkening skin</li> <li>• Pain and difficulty with urination</li> <li>• Kidney damage</li> <li>• Seizures</li> <li>• Finger and toe nail changes</li> </ul>	<ul style="list-style-type: none"> <li>• Hives</li> <li>• Skin rash</li> <li>• Sudden high fever</li> </ul>

**Fludarabine (Fludara®) – Chemotherapy drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Low number of red blood cells (anemia)</li> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Feeling tired</li> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Weak immune system</li> <li>• Pneumonia</li> <li>• Infection</li> <li>• Bleeding</li> <li>• Pain</li> <li>• Electrolyte imbalance</li> </ul>	<ul style="list-style-type: none"> <li>• Diarrhea</li> <li>• Mouth sores</li> <li>• Skin rash</li> <li>• Fever</li> <li>• Swelling of hands and feet</li> <li>• Numbness and tingling in hands and/or feet</li> <li>• Loss of appetite</li> </ul>	<ul style="list-style-type: none"> <li>• Changes in vision</li> <li>• Feeling nervous or anxious</li> <li>• Confusion</li> <li>• Cough</li> <li>• Difficulty breathing</li> <li>• Feeling weak</li> <li>• Severe brain injury which can lead to death</li> <li>• Kidney damage that could require dialysis</li> <li>• Coma</li> <li>• New (secondary) cancers</li> </ul>

**Rabbit Anti-Thymocyte Globulin (r-ATG, Thymoglobulin®) – Chemotherapy drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Fever</li> <li>• Chills</li> <li>• Low number of red blood cells (anemia)</li> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Weak immune system</li> <li>• Bleeding</li> <li>• Infection</li> <li>• Skin rash</li> <li>• Joint ache and pain</li> </ul>	<ul style="list-style-type: none"> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Diarrhea</li> <li>• Headache</li> <li>• Sweating</li> <li>• Back pain</li> <li>• Severe itching</li> <li>• Feeling tired</li> <li>• Loss of appetite</li> </ul> <p>Serum sickness with:</p> <ul style="list-style-type: none"> <li>• Severe skin rash</li> <li>• Mouth sores</li> <li>• Vaginal sores, if female</li> <li>• Pain and swelling in joints</li> <li>• Kidney damage</li> </ul>	<ul style="list-style-type: none"> <li>• Stomach (belly) pain</li> <li>• Feeling dizzy</li> <li>• High blood pressure</li> <li>• Blisters</li> <li>• Muscle pain</li> <li>• Herpes simplex infection</li> <li>• Throat inflammation (sore, red, swollen throat)</li> <li>• Kidney failure</li> </ul> <p>Severe allergic reaction which may cause:</p> <ul style="list-style-type: none"> <li>• Life-threatening drop in blood pressure</li> <li>• Wheezing</li> <li>• Difficulty breathing</li> <li>• Severe hives</li> </ul>

**Thiotepa – Chemotherapy drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Low number of red blood cells (anemia)</li> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Bleeding</li> <li>• Infection</li> <li>• Diarrhea</li> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Mouth and throat sores</li> <li>• Liver damage</li> <li>• Temporary hair loss</li> <li>• Loss of appetite</li> <li>• Infertility (inability to have children)</li> </ul>	<ul style="list-style-type: none"> <li>• Change in vision</li> <li>• Swelling in lower legs and feet</li> <li>• Abnormal liver tests</li> <li>• Skin rash</li> <li>• Skin darkening</li> </ul>	<ul style="list-style-type: none"> <li>• Red face</li> <li>• Painful and difficult urination</li> <li>• Kidney damage</li> <li>• Yellow tint to skin and eyes (jaundice)</li> <li>• Headache</li> <li>• Feeling dizzy</li> <li>• Seeing or hearing things that are not really there</li> <li>• Confusion</li> <li>• Disorientation</li> <li>• Seizures</li> <li>•</li> <li>• Temporarily increased levels of liver enzymes</li> <li>• Finger or toe nail changes</li> <li>• New (secondary) cancers</li> </ul>

**Total Body Irradiation (TBI) – Radiation therapy**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Diarrhea</li> <li>• Stomach (belly) pain</li> <li>• Feeling tired</li> <li>• Low number of red blood cells (anemia)</li> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Bleeding</li> <li>• Infection</li> <li>• Temporary hair loss</li> <li>• Cataracts</li> <li>• Slow growth in children</li> <li>• Infertility (inability to have children)</li> <li>• Thyroid problems or diabetes</li> <li>• Mouth sores</li> </ul>	<ul style="list-style-type: none"> <li>• Lung inflammation and pneumonia</li> <li>• Red skin color</li> <li>• Abnormal liver tests</li> </ul>	<ul style="list-style-type: none"> <li>• Pain and swelling under the chin</li> <li>• Difficulty swallowing</li> <li>• Back pain</li> <li>• New (secondary) cancers</li> <li>• Lung damage</li> <li>• Kidney damage</li> </ul>

Risks of Drugs Used to Prevent GVHD

You will get medicines to help prevent GVHD after your transplant. The side effects of the GVHD drugs are listed below. These side effects usually stop when you’re done taking the medicines.

**Cyclophosphamide (Cytosan®) – GVHD prevention drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Bleeding</li> <li>• Infection</li> <li>• Blood in urine</li> <li>• Weak immune system</li> <li>• Temporary hair loss</li> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Headache</li> <li>• Dizziness</li> <li>• Loss of appetite</li> <li>• Sores in mouth or on lips</li> <li>• Diarrhea</li> <li>• Menstrual periods stop in females</li> <li>• Low sperm count in males</li> </ul>	<ul style="list-style-type: none"> <li>• Low number of red blood cells (anemia)</li> <li>• Temporary darkening of finger and toe nail beds</li> <li>• Acne</li> <li>• Feeling tired</li> <li>• Damage to unborn baby or miscarriage</li> <li>• Birth defects</li> </ul>	<ul style="list-style-type: none"> <li>• Lung scars, with cough and shortness of breath</li> <li>• Severe heart muscle injury and death</li> <li>• New (secondary) cancers</li> </ul>

**MESNA – Bladder damage prevention drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Diarrhea</li> <li>• Stomach (belly) pain</li> <li>• Feeling tired</li> <li>• Headache</li> <li>• Pain in joints</li> <li>• Pain in arms and hands, legs and feet</li> <li>• Change in the way things taste</li> <li>• Skin rash</li> <li>• Hives</li> </ul>	<ul style="list-style-type: none"> <li>• Low blood pressure</li> <li>• Feeling dizzy or faint</li> </ul>	

**Sirolimus – GVHD prevention drug**

<p><b>Likely</b></p> <p>(May happen in more than 20% of patients)</p>	<p><b>Less Likely</b></p> <p>(May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b></p> <p>(May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Diarrhea and/or constipation</li> <li>• High blood pressure</li> <li>• Tremor (shaking)</li> <li>• Infection</li> <li>• Fever</li> <li>• Feeling weak</li> <li>• Feeling tired</li> <li>• Abnormal kidney tests</li> <li>• Low number of red blood cells (anemia)</li> <li>• Headache and/or back pain</li> <li>• Joint or muscle pain</li> <li>• Stomach or belly pain</li> <li>• High levels of sugar in the blood</li> <li>• High cholesterol</li> <li>• Swelling in feet and lower legs</li> <li>• Weight gain</li> <li>• Acne</li> </ul>	<ul style="list-style-type: none"> <li>• Chest pain</li> <li>• Insomnia (unable to sleep)</li> <li>• Low level of magnesium, potassium and/or phosphate</li> <li>• Abnormal liver tests</li> <li>• Skin rash or hives</li> <li>• Upset stomach (heartburn)</li> <li>• Throat inflammation (red, sore, swollen throat), going down to stomach</li> <li>• Shortness of breath</li> <li>• Low number of white blood cells</li> <li>• Low number of blood platelets</li> <li>• Bleeding</li> <li>• Infections</li> <li>• Slow wound healing</li> <li>• Unwanted hair growth</li> </ul>	<ul style="list-style-type: none"> <li>• Low blood pressure</li> <li>• Lung problems, including asthma</li> <li>• Loss of appetite</li> <li>• Serious infections</li> <li>• Fast heartbeat</li> <li>• Heart damage</li> <li>• Blood clots</li> <li>• Kidney failure</li> <li>• Bone thinning (osteoporosis) or loss (necrosis) which may cause broken bones</li> <li>• New (secondary) skin cancers</li> </ul>

**Mycophenolate Mofetil (MMF, CellCept®) – GVHD prevention drug**

<p><b>Likely</b> (May happen in more than 20% of patients)</p>	<p><b>Less Likely</b> (May happen in fewer than 20% of patients)</p>	<p><b>Rare, but Serious</b> (May happen in fewer than 2% of patients)</p>
<ul style="list-style-type: none"> <li>• Birth control pills may not work</li> <li>• Birth defects</li> <li>• Damage to unborn baby or miscarriage</li> <li>• Nausea (feeling sick to your stomach)</li> <li>• Throwing up (vomiting)</li> <li>• Diarrhea</li> <li>• Stomach (belly) pain</li> <li>• Headache</li> <li>• Low number of white blood cells</li> <li>• Infection</li> <li>• Swelling of hands, feet, or lower legs</li> </ul>	<ul style="list-style-type: none"> <li>• Low number of red blood cells (anemia)</li> <li>• Skin rash</li> <li>• Insomnia (unable to sleep)</li> <li>• Feeling dizzy</li> <li>• Hand shaking (tremors)</li> </ul>	<ul style="list-style-type: none"> <li>• Difficulty breathing</li> <li>• Abnormal bruising</li> <li>• Fast heartbeat</li> <li>• Feeling very tired</li> <li>• Feeling weak</li> <li>• Blood in stool</li> <li>• Blood in vomit</li> <li>• New (secondary) cancers</li> <li>• Progressive multifocal leukoencephalopathy (a disease that damages the brain and may lead to death)</li> </ul>

**Risks and Toxicities Related to Transplant**

The following problems may happen because of your transplant. These risks may happen with all allogeneic transplants, whether they are part of a study or not. The risks include:

Complications with Central Venous Catheter:

The most common problems with central venous catheters are: 1) blood clots in the catheter and 2) infection. Your doctor will inject medicines into the catheter to dissolve a clot or treat an infection. If the medicines don't work, the catheter might be replaced with a new one.

Slow Recovery of Blood Counts:

The red blood cells, white blood cells, and platelets can be slow to recover after a transplant. Until your blood counts recover, you'll be at risk for bleeding and infection, and you'll need blood and platelet transfusions.

Graft Failure:

We'll check your blood often to see how well the stem cells (the "graft") are growing inside your body. If the graft isn't growing well or at all (graft failure), we'll give you medicines to help the stem cells grow. You may also need a second transplant.

Past experience suggests that there can be a 10 - 15% chance of graft failure. If your graft fails, you'll stop being in this study and receive the standard care for SCD.

Graft-Versus-Host Disease (GVHD):

GVHD happens when the donor cells see your body as foreign and attack it. In most cases, GVHD can be successfully treated. Sometimes GVHD is serious or difficult to treat, and may lead to death. You'll be watched closely for GVHD and given drugs to help prevent and treat it.

Acute GVHD, which can happen 0 – 3 months after transplant, may cause skin rash, nausea, vomiting, diarrhea, abdominal pain, problems with your liver, and an increased risk of infection.

Chronic GVHD, which can happen 3 months or later after transplant, may produce skin rashes, hair loss, thickened dry skin, dry eyes, dry mouth, liver disease, weight loss, diarrhea, and an increased risk of infection.

To confirm the diagnosis of acute or chronic GVHD, your doctor may do a biopsy of your skin, gut, or liver. A biopsy is a small sample of your tissue to look at under the microscope.

Damage to the Vital Organs in Your Body:

The transplant may cause problems with your organs such as the heart, lungs, liver, gut, kidneys, bladder, or brain. The kidneys and liver are most likely to be damaged.

Some patients will experience serious lung problems from an infection, from chronic GVHD or from the chemotherapy and radiation.

Serious Infections:

Full and complete recovery of your immune system may take several months. During this time, there is an increased risk of infection. We'll give you drugs to reduce the chance of infection, but these treatments don't always work. If you get an infection, you may have to stay in the hospital longer or be re-hospitalized. Most infections can be treated, but some result in death.

Recurrence of Disease and Graft Rejection:

There is a risk that the new marrow will fail to “take” and won’t grow after your transplant. This is called **graft rejection**. If this happens, your own marrow will recover and sickle cell disease will come back. Pain crises or other complications might also return. Very rarely, other complications from graft rejection can happen including serious infection and the need for a blood transfusion.

Damage to Central Nervous System (CNS):

The transplant may affect your central nervous system (CNS). Your CNS includes your brain and spine. We’ll watch you closely after your transplant for any side effects to your brain or spine.

Risk of Death:

Side effects of an allogeneic transplant can be very serious and possibly lead to death. Death can occur either as a result of the medications you receive to prepare your body for transplant or from a complication of transplant. We’ll do everything we can to make the transplant as safe as possible for you.

Reproductive Risks:

The drugs used in this research study may damage your reproductive organs and affect your ability to have children. We don’t know the exact risk of sterility (inability to have children) caused by taking the study drugs.

You should talk to a specialist about your options for fertility preservation. Your options may include storing your sperm or eggs, or tissue from your ovary or testes. We’ll refer you to a fertility preservation center before your transplant.

The treatments in this study have not been proven to be safe at any stage of pregnancy, including when the sperm enters the egg (conception).

- If you’re female:
  - Your menstrual cycle might become irregular or permanently stop if you’ve gone through puberty.
  - You must use 2 effective methods of birth control if you’re sexually active (having sexual intercourse with a male partner) during your transplant. You must continue to use 2 effective birth control methods or refrain from all acts of vaginal sex (abstinence) until you’re finished with your GVHD prevention medicines or GVHD treatment or 12 months after your transplant (whichever comes last).

Examples of effective birth control include:

1. Consistent use of birth control pills
2. Injectable birth control methods (Depo-Provera, Norplant)
3. Tubal sterilization or male partner who has undergone a vasectomy
4. Placement of an IUD (intrauterine device)
5. Use a diaphragm with contraceptive jelly every time you have sex and/or
6. Use condoms with contraceptive foam every time you have sex.

Tell your doctor right away if you become pregnant during the study.

▪ **If you're male:**

- If you're sexually active (having sexual intercourse with a female partner), you or your partner must use 2 effective methods of birth control during your transplant. You or your partner must continue to use 2 effective birth control methods or refrain from all acts of vaginal sex (abstinence) until you are finished with your GVHD prevention medicines or GVHD treatment or 12 months after your transplant (whichever comes last).

Examples of effective birth control include:

1. Consistent use of birth control pills
2. Injectable birth control methods (Depo-Provera, Norplant)
3. Tubal sterilization or male partner who has undergone a vasectomy
4. Placement of an IUD (intrauterine device)
5. Use a diaphragm with contraceptive jelly every time you have sex and/or
6. Use condoms with contraceptive foam every time you have sex.

Tell your doctor right away if your partner becomes pregnant during the study.

Check with your doctor to understand more about these risks.

## **Other Risks**

### Quality of Life Surveys:

There are a few risks from completing the quality of life surveys. Some of the questions or topics may upset you. You may feel emotional or that your privacy is lost. Talk to your doctor about your privacy concerns. We can put you in touch with a counselor or trained support specialist, if needed.

### Risks of Blood Draws:

There are no major risks with blood draws. Having your blood drawn can be uncomfortable and may cause a bruise. In rare cases, a blood draw can cause fainting. Only trained people will draw your blood.

### Unforeseen Risks:

Other new risks might appear at any time during the study. These risks might be different from what is listed in this Consent Form. There may be some unknown or unanticipated discomforts or risks associated with this treatment in addition to those specified above, but every precaution will be taken to assure your personal safety and to minimize discomforts.

### Other Treatments or Medicines:

Some medicines react with each other, so it's important to tell the study doctor or staff about any other drugs, treatments, or medicines you're taking. This includes non-prescription or over-the-counter medicines, vitamins, and herbal treatments.

It's also important that you tell the study staff about any changes to your medicines while you're in the study.

For more information about risks and side effects, ask your study doctor.

## **7. Other Treatments**

It's optional to join this study. If you choose not to join, you may still receive an allogeneic transplant to treat your disease. The treatment you'd receive could be very similar to what you'd receive in this study.

Your study doctor will talk with you about your options. Your other choices may include:

- Other types of transplant that use different doses of medicines (check with your doctor)
- Other clinical trials that use mismatched related (parent, brother, sister or other family member) donors, unrelated donors or other stem cell sources (check with your doctor)

- Standard care for SCD (such as hydroxyurea or blood transfusions)
- Another experimental treatment that is not a transplant

Every treatment option has risks and benefits. Your study doctor will discuss the options, including the risks and benefits, with you.

If you decide not to join this study, your medical care will not be affected in any way.

## **8. Possible Benefits**

We don't know if the treatments in this study will make your SCD better. If the transplant works well, you may not have any more symptoms of SCD such as serious pain.

The study results will help doctors know what works best to treat SCD. This knowledge could help SCD patients in the future.

## **9. New Information Available During the Study**

The study doctors could learn new information about the risks and benefits of allogeneic transplant and the study medicines while the study is going on. If this happens, they'll tell you about it. Your doctor may decide to stop your participation. You may decide that you don't want to continue in the study.

If you decide to stop being in the study, your doctor will discuss other treatment options with you.

## **10. Privacy, Confidentiality and Use of Information**

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your study number is not related to your name, social security number or medical record number at **[insert facility name]**.

Information about your transplant from your original medical records may be seen or sent to national and international transplant registries, including:

- The Center for International Blood and Marrow Transplant Research (CIBMTR)
- The National Marrow Donor Program (NMDP)

- The Food and Drug Administration (FDA)
- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
- Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
- Data Warehouse Consultants (DWC) which is an agent of Emory University that will manage the pain diary. DWC will have access to your phone number, email address, IP Address and data that is entered in the pain diary application.
- Researchers and staff members at Vanderbilt University for central review of brain MRI/MRA images.
- Dr. Allistair Abraham and laboratory staff at Children’s National Medical Center
- Other authorized study organizations

We’ll not identify you by name in any publications or reports that come from these organizations or groups.

## **11. Ending Your Participation**

The study doctor or the study sponsor may stop the study at any time. We may ask you to leave the study if you don’t follow directions or if you suffer from side-effects of the treatment. If you are asked to leave the study, the reasons will be discussed with you.

Possible reasons to end your participation in this study include:

- You don’t meet the study requirements.
- You need a medical treatment not allowed in this study.
- The study doctor decides that it would be harmful to you to stay in the study.
- You’re having serious side-effects.
- You become pregnant.
- You can’t keep appointments or take study drugs as directed.
- The study is stopped for any reason.

## **12. Physical Injury as a Result of Participation**

It's important that you tell your study doctor or study staff if you feel that you've been hurt or injured because of taking part in this study.

You'll get medical treatment if you're injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. This study will not pay for this medical treatment.

In case of injury resulting from this study, you don't lose any of your legal rights to seek payment by signing this form.

## **13. Compensation or Payment**

If you speak English and are 15 years or older, you will be asked to complete a pain diary when first enrolled and then 1 and 2 years later. If you complete the pain diary twice daily, you will receive a \$50 gift card. This compensation will be the same for all three of the 28-day reporting periods. The potential compensation for completing the pain diary at all of these time points is \$150 (\$50 for each 28-day reporting period).

## **14. Costs & Reimbursements**

Most of the visits for this study are standard care for SCD patients who have an allogeneic transplant, and will be billed to your insurance company.

You and/or your health insurance company will need to pay for some or all of the costs of standard treatment in this study.

You will not be charged for the collection of optional samples.

## **15. Ethical Review**

The ethical aspects of this research study have been reviewed and approved by [name of IRB].

## **16. For More Information**

If you'd like more information about this study, or if you have any problems while you're participating in this study, you can contact the study doctor or staff.

They may be contacted at the telephone numbers listed here:

[Insert name and contact details]

A description of this clinical trial will also 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.

## **17. Independent Contact**

If you wish to speak to someone not directly involved in the study, or have any complaints or questions about your rights as a research participant, you may contact:

**[Insert appropriate contact details]**

## 18. OPTIONAL Blood Samples for Trial-related Research Studies

**This section of the Consent Form is about providing optional blood samples for use in additional research.**

You can choose to give blood samples for optional trial-specific studies if you want to. You can still be a part of the main study even if you say “no” to giving optional blood samples for these studies. Please mark your choice at the end of this section.

Researchers are trying to learn more about how the human body recovers in SCD patients after transplant. This research is meant to gain knowledge that may help people in the future and make transplants even more successful.

**If you agree to provide optional blood samples, here is what will happen:**

- We’ll take the sample from your catheter or by a vein in your arm. We will collect 40mL (about 8 teaspoons) if you are 15 years or older, or 24-40 mL (about 4-8 teaspoons) if you are 5 - 14 years old. We’ll collect this sample when you have your check-up before treatment starts and 28, 60, 100, 180, and 365 days after your transplant.
  - These blood samples will be shipped on the day of collection to Children’s Research Institute laboratory for an important study related to this trial. All research samples will be given a bar code that cannot be linked to you by researchers testing your samples. Your research samples will be sent to Children’s Research Institute laboratory to be used for this research.
  - Your name and other information that could directly identify you (such as address or social security number) will not be used. Researchers have a duty to protect your privacy and to keep your information confidential.

### **Benefits**

The research that may be done with your blood samples is not designed specifically to help you. The benefits of research using blood samples include learning more about how the immune system recovers in SCD patients after transplant.

### **Risks**

There is a small risk of an infection or fainting from the blood draw.

A possible risk is the loss of confidentiality about your medical information. We will do our best to make sure that your personal information is kept private. The chance that this information will be given to someone else is very small.

Some general things to think about when letting us collect your blood samples for research are:

- The choice to let us collect your blood samples is up to you. No matter what you decide to do, it will not affect your care.

- If you decide now that your blood samples can be collected for research, you can change your mind at any time. Just contact your study doctor in writing and let him or her know that you do not want us to collect anymore of your blood samples for research. His/her mailing address is on the first page of this form. Then any further optional blood samples needed for this research will not be collected. However, samples that have already been collected cannot be taken back or destroyed.
- People who do research on these blood samples may need to know more about your health. While the study doctor or others involved in running this study may give the researchers reports about your health, they will not give them your name, address, phone number, or any other information that will let the researchers know who you are.
- Your blood will be used only for research and will not be sold. The research done with your blood may help to develop new products in the future. You will not get paid for any samples or for any products that may be developed from current or future research.
- Reports about research done with your blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

### **Making Your Choice**

Please read each sentence below and think about your choice. After reading each sentence, please indicate your choice below. If you have any questions, please talk to your doctor or nurse, or call our research review board at [telephone number].

No matter what you decide to do, it will not affect your care.

**You can change your mind at any time about allowing us to use your samples for research. However, samples that have already been collected cannot be taken back or destroyed.**

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## Statement of Consent for Optional Blood Samples for Trial-Related Research Studies

The purpose of collecting optional blood samples, the procedures involved, and the risks and benefits have been explained to me. I have asked all the questions I have at this time and I have been told whom to contact if I have more questions. I have been told that I will be given a signed copy of this consent form to keep. I understand that I do not have to allow the collection and storage of my blood samples for study-specific research. If I decide to not let you collect research samples now or in the future, it will not affect my medical care in any way.

I voluntarily agree that optional blood samples may be collected and that my blood samples can be sent to the Children’s Research Institute Laboratory for research to learn about immune system recovery in sickle cell disease patients after transplant.

- I do agree to give blood samples for study-specific research.
- I do not agree to give blood samples for study-specific research.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Health Insurance Portability and Accountability Act 1 (HIPAA<sup>1</sup>) Authorization to use and disclose individual health information for research purposes**

**A. Purpose**

As a research participant, I authorize the Principal Investigators and the researcher’s staff to use and disclose my individual health information for the purpose of conducting the research study:

(List PI and research staff names)

**B. Individual Health Information to be Used or Disclosed**

My individual health information that may be used or disclosed to do this research includes:

- Demographic information (for example: date of birth, sex, weight).
- Medical history (for example: diagnosis, complications with prior treatment).
- Findings from physical exams.
- Laboratory test results obtained at the time of work up and after treatment (for example: blood tests, biopsy results).

**C. Parties Who May Disclose My Individual Health Information**

The researcher and the researcher’s staff may collect my individual health information from:

(List hospitals, clinics or providers from which health care information can be requested).

**D. Parties Who May Receive or Use My Individual Health Information**

The individual health information disclosed by parties listed in item c and information disclosed by me during the course of the research may be received and used by the following parties:

- Principal Investigator and the researcher’s staff  
(List names)

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<sup>1</sup> HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

- Study Sponsors  
National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH); Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)
- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments.
- Data Warehouse Consultants (DWC) which is an agent of Emory University that will manage the pain diary. DWC will have access to your phone number, email address, IP Address and data that is entered in the pain diary application.
- Dr. Allistair Abraham and laboratory staff at Children’s National Medical Center

**E. Right to Refuse to Sign this Authorization**

I do not have to sign this authorization. If I decide not to sign the authorization, I will not be allowed to participate in this study or receive any treatment related to research that is provided through the study.

My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

**F. Right to Revoke**

I can change my mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision.

If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

**G. Potential for Re-disclosure**

My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected.

Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

**H. This authorization does not have an expiration date.**

**Principal Investigator(s)**

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Address: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_

- I've read and understood this Consent Form. The nature and purpose of the research study has been explained to me.
- I've had the chance to ask questions, and understand the answers I've been given. I understand that I may ask questions at any time during the study.
- I freely agree to be a participant in the study.
- I understand that I may not directly benefit from taking part in the study.
- I understand that, while information gained during the study may be published, I won't be identified and my personal results will stay confidential.
- I've had the chance to discuss my participation in this research study with a family member or friend.
- I understand that I can leave this study at any time, and doing so will not affect my current care or prevent me from receiving future treatment.
- I understand that I'll be given a copy of this signed consent form.

\_\_\_\_\_  
Participant or Parent/Guardian Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant or Parent/Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

\_\_\_\_\_  
Counseling Physician

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Counseling Physician

\_\_\_\_\_  
Date