Medical College of Wisconsin and Froedtert Hospital
PARENTAL CONSENT/CHILD ASSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

Bridging Study: A Phase 2 Study Investigating Clofarabine, Cyclophosphamide and Etoposide for Children, Adolescents, and Young Adults (AYA) with Acute Leukemia and Minimal Residual Disease

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Child/Adult Subject: You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, possible risks and benefits to you, your choices, and other important information. If there is anything that you do not understand, please ask questions. Then you can decide if you want to join this study or not. If you are under 18, your parent or guardian also needs to give their permission for you to join this study.

Parent/Guardian: Your child is invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, and possible risks and benefits to your child. If there is anything you do not understand, please ask questions. Then you can decide if you want your child to join this study or not.
The word "you" in this form refers to your child.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

Acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML) remain two of the most common forms of leukemia diagnosed in both children and adults, as well as two of the most common hematological diseases for which allogeneic hematopoietic cell transplantation (HCT) is currently used.

There is mounting evidence to support that for patients in hematological remission, the presence of minute amounts of leukemia (known as minimal residual disease (MRD), identified immediately prior to HCT is associated with higher rates of ALL and AML relapse following HCT.

We are asking if you want to participate in a research study of an experimental treatment intended to reduce pre-transplant disease burden by achieving a pre-transplant MRD negative state. You are being asked to take part in this research study for the following reasons:

- You have been diagnosed with high risk acute lymphoblastic leukemia (ALL) or acute myelogenous leukemia (AML);
- Your planned treatment involves receiving an allogeneic hematopoietic cell transplantation (HCT); and
- You have evidence of minimal residual disease (MRD)

A total of about 50 people are expected to participate in this study at the following institutions:

- Medical College of Wisconsin/Froedtert Hospital, Milwaukee, WI
- Children's Hospital of Wisconsin, Milwaukee, WI
- Nationwide Children's Hospital, Ohio
- University of Wisconsin, Madison, WI

We are expecting to treat about 25 children and adults at the Medical College of Wisconsin/Froedtert Hospital/Children's Hospital of Wisconsin.

The Director of the study is Michael J. Burke, MD in the Department of Pediatric Oncology, Hematology, and Bone Marrow Transplant. A study team works with Dr. Burke. You can ask who these people are.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A research study is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The goal of this Phase 2 study is to assess the combination of Clofarabine, Cyclophosphamide, and Etoposide in their ability to lower MRD without causing toxicities which could possibly delay HCT. We also want to learn if this treatment will prevent relapse and whether it will help high risk ALL/AML patients with MRD prior to HCT to live longer.

Everyone in this study will receive a combination of Clofarabine, Cyclophosphamide, and Etoposide which are approved by the U.S. Food and Drug Administration for use in patients but not with your condition. We don't know if this study will help you. Your condition may get

better but it could stay the same or even get worse. We hope the information from this study will help us develop a better treatment for MRD prior to HCT in the future.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Screening Procedures

If you decide to join the study, you will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- A medical history
- Physical exam including height and weight
- Vital signs (blood pressure, pulse, temperature)
- Blood tests to check various organ functions
- Urine tests
- Echocardiogram/MUGA
- Pregnancy test (if you are a woman who could have children)
- Performance status (Karnofsky or Lansky)
- Bone marrow aspirate

Note: If you have recently had any of the required screening exam tests or X-rays as part of your routine medical care, your doctor will, whenever possible, use the results of the previously performed studies in determining your eligibility for this study.

Tests on the Bone Marrow

Examinations of the bone marrow will be performed routinely and may be done at the discretion of your study doctor. You have already had many tests of your bone marrow for your previous treatment of AML or ALL. Many children receive some form of sedation or anesthesia during this procedure. A small area over your hip bone on the back will be cleaned and numbed with lidocaine and/or with an anesthetic cream. Approximately 2 teaspoons of bone marrow will be withdrawn through a needle inserted into the bone. The test is painful, especially when the bone marrow is withdrawn. There is also a small risk of bleeding or infection from this procedure.

If the screening information shows that you meet the requirements, then you will be able to start the study. If the screening information shows that you cannot be in the research study, the study doctors will discuss other options with you and/or refer you back to your regular doctor.

Summary of Study Procedures

During the Study: If the exams, tests and procedures show that you can be in the study, and you choose to take part, the administration of the study drugs will follow institutional drug and supportive care guidelines.

Treatment Plan (Regardless of Diagnosis): A treatment cycle lasts about 28 days with the actual drugs all being given on Days 1 through 5. Only 1 treatment course is permitted. The treatment is summarized in the following table:

Drug	How The Drug Will Be Given?	Day
Clofarabine	IV over 2 hours (given at Hours 0 to 2)	1-5
Etoposide	IV over 2 hours (given at Hours 2 to 4)	1-5
Cyclophosphamide	IV over 30-60 minute infusion (given at Hours 4 to 5)	1-5

The intent of this study design is for all patients to receive and complete one course of therapy. Patients who exhibit signs of disease progression or experience an unacceptable toxicity will be discontinued from treatment.

Methods For Giving Drugs

Various methods will be used to give drugs to subjects.

- PO – Drug is given by tablet or liquid swallowed through the mouth.
- IV – Drug is given using a needle or tubing inserted into a vein. It can be given by IV push over several minutes or by infusion over minutes or hours.
- IM – Drug is given using a needle injected into the muscle.
- SQ – Drug is given by injecting a needle into the tissue just under the skin.
- IT – Intrathecal - Drug used to treat the brain and spinal cord is given using a needle inserted into the fluid surrounding the spinal cord.

Drugs given for this study will all be given by IV or through your Central Line as described below.

Central Line

For drugs to be given by vein, your doctor will likely recommend that you have a central venous line placed. A central line is a type of tubing inserted into a large vein in the chest by a surgeon during a short operation. The central line is used to administer chemotherapy drugs and to withdraw small amounts of blood for testing during treatment. How the tubing is inserted and all the risks associated with central lines will be explained to you, and all of your questions about the central line will be answered, when you sign a separate consent for the central line. A

description of the types of central lines is available at your local institution or in the COG Family Handbook for Children with Cancer.

Medical Tests During Treatment

While you are on study treatment the following standard medical tests will be done to monitor for response to therapy as well as side effects related to treatment. These include the following and may be done more frequently because you are in the study.

Daily Assessments and Labs (Day 1-5)

- Physical exams with vital signs
- Blood tests to check your organ function

You will have regular medical appointments throughout treatment.

Study Tests and Procedures

The following tests will be done even if were not in this study because you are going on to HSCT. You may have these tests done more frequently because you are in the study.

Weekly Assessments and Labs (Day 6-30)

- Physical exams with vital signs
- Blood tests to check your organ function

Bone Marrow Test: A bone marrow evaluation to determine study response and remission status will be performed on study Day 30 or upon adequate blood count recovery, whichever occurs first. If the marrow results show low cell counts, you may need to repeat this test at Day 42. Your doctor will let you know if you should repeat this test.

Final Study Visit

If you begin protocol therapy, you will be followed for safety monitoring until the start of a new therapy (i.e. transplant preparative regimen) or until Day 60, whichever occurs earlier. Your doctor will need to check to see how you are doing. The doctor will ask you how you feel, if you have trouble doing your daily routine, and what drugs you are taking. You will also have the following tests done:

Weekly Assessments and Labs (Day 30-60)

- Physical exams with vital signs
- Blood tests to check your organ function

B2. HOW LONG WILL I BE IN THE STUDY?

Subjects in this clinical trial may receive one treatment course on this study. After treatment, subjects will have follow-up examinations and medical tests.

After completing the treatment on this study we would like to continue to collect some medical information about how you are doing for as long as you are willing to let us or until the study is closed to enrollment and all study activities have been completed. We will collect information on how your AML or ALL and transplant care are doing, and what kind of therapy you may be getting. By keeping in touch with you after you complete treatment, we can better understand the long-term effects of the study treatments.

B3. CAN I STOP BEING IN THE STUDY?

You are free to withdraw from the study at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the study doctor.

You can stop taking part in the study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your regular doctor first. They will help you stop safely.

Your doctor or the researcher may decide to take you off this study under the following circumstances:

- If he/she believes that it is in your best interest
- Your disease does not improve or gets worse during treatment
- You experience side effects from the treatment that are considered too severe
- You need a treatment that is not allowed on this study
- If new information becomes available that shows that another treatment would be better for you
- You are not able to follow study-related treatment instructions
- If the whole study is stopped

It is important to tell the study doctor if you are thinking about stopping so any risks from the study drugs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE STUDY?

If you become pregnant or father a child during this study, contact your doctor immediately to discuss the requirements for pregnancy outcome follow-up.

Female subjects will be given instructions for discontinuation of study medication.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

There are risks to taking part in any research study. There is a risk that the treatment plan will not cure the cancer or that the cancer can go away after the treatment and then come back at a later date. There also may be problems (side effects) we do not know about yet from the drugs given in this therapy, or how they combine with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the study for problems (side effects). **You need to tell the study doctor or a member of the study team immediately if you experience any problems, side effects, or changes in your health.**

C2. RISKS OF STUDY DRUGS

The research drugs themselves may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away. Many go away soon after you stop taking the drug.

Each drug may have a unique set of side effects. Side effects related to drugs occur in people at different rates or frequencies. The following tables (drug monographs) provide details of the known and expected side effects associated with the drugs given in this therapy.

Risks and Side Effects Related to the Clofarabine Include Those Which Are:		
Likely	**Less Likely**	**Rare But Serious**
• A fast heartbeat which may cause pain in the chest • A feeling of extreme tiredness not relieved by sleep • A decrease in blood pressure • Pain in the abdomen (belly) • Constipation • Diarrhea • Nausea and/or vomiting • Headache • Fever which may also come with shaking chills • Anxiety • Fever with a low white blood cell count which could mean that you have an infection and might require hospitalization and treatment with antibiotics • Loss of appetite	• Fluid build-up in the tissues • Pain or burning at the site of the injection • Dizziness • Sleepiness • Tremor (shakiness usually of the hands) • Changes to your emotions such that you feel depressed, anxious, irritable or confused • High blood pressure • Cough or shortness of breath • Reddening of the face with feelings of warmth when the drug is infusing • Sore throat	• The rapid death of large numbers of tumor cells which can cause the potassium and phosphate salts and the uric acid in the blood to rise quickly and this could lead to a life-threatening irregular heart beat or damage to the kidneys. • Severe loss of water from the body (dehydration) which if untreated may cause low blood pressure and severe loss of salts such as sodium and potassium from the body and could lead to the kidneys failing which could be life-threatening

Risks and Side Effects Related to the Clofarabine Include Those Which Are:		
Likely	**Less Likely**	**Rare But Serious**

• Elevation in the blood of certain enzymes found in the liver which may mean the liver is not working as well as normal
• Damage to the sac around the heart which can lead a build-up of fluid around the heart which may be painful and affect the ability of the heart to work normally but in most cases is only mild and temporary
• Temporary change to the heart such that it does not pump the blood as well which may make you tired, weak, feel short of breath, and retain fluid
• Skin rash with itching and redness or inflammation
• Infections including those caused by bacteria, virus, and fungus and can be found in the lung, the blood, the skin and other places in the body
• Bloody nose
• Fewer white blood cells, red blood cells and platelets in the blood
  ○ a low number of white blood cells can make it easier to get infections
  ○ a low number of red blood cells can make you feel tired and weak
  ○ a low number of platelets causes you to bruise and bleed more easily
	• Inflammation and/or sores in the mouth (and/or throat and /or esophagus, the tube that leads from the mouth to the stomach) that may make swallowing difficult and are painful (painful mouth sores)
	• Pain including back or arm or leg pain
	• Enlarged liver which could lead to an elevation in the blood of bilirubin which is found in the liver and if present in large amounts can lead to a yellow appearing skin (jaundice)
	• Weight loss
	• Aches and pains in the muscles and joints
	• Bleeding from the bladder or gums
	• Fluid build-up in the lungs that can make you feel short of breath
	• Severe rash with redness and pain on the palms of the hand and soles of the feet
	• Red spots on the skin from low platelets
	• High levels of uric acid in the blood which could damage the kidneys
	• Increased levels of a chemical (creatinine) in the blood which could mean kidney damage
		• Capillary leak syndrome: A condition in which fluid and proteins leak out of tiny blood vessels and flow into surrounding tissues, resulting in dangerously low blood pressure. Capillary leak syndrome may lead to multiple organ failure such as kidney, heart or liver failure and shock.
		• Inflammation of the pancreas (an organ in the abdomen which produces insulin and certain digestive chemicals) which may affect the function of the pancreas and which may cause pain in the abdomen (belly) which can be severe and may increase the blood sugar

Risks and Side Effects Related to Cyclophosphamide Include Those Which Are:		
Likely	**Less Likely**	**Rare But Serious**

• Loss of appetite
• Nausea
• Vomiting
• Fewer white blood cells in the blood.
  ○ a low number of white blood cells may make it easier to get infections
• Hair loss
• Decreased ability of the body to fight infection
• Absence or decrease in the number of sperm which may be temporary or permanent which may decrease the ability to have children
	• Abnormal hormone function which may lower the level of salt in the blood
	• Abdominal pain
	• Diarrhea
	• Fewer red blood cells and platelets in the blood
	  ○ a low number of red blood cells may make you feel tired and weak
	  ○ a low number of platelets may cause you to bruise and bleed more easily
	• Bleeding and inflammation of the urinary bladder
	• Absence or decrease monthly periods which may be temporary or permanent and which may decrease the ability to have children
	• Temporary blurred vision
	• Nasal stuffiness with IV infusions
	• Skin rash
	• Darkening of areas of the skin and finger nails
	• Slow healing of wounds
	• Infections
		• Heart muscle damage which may occur with very high doses and which may be fatal
		• Abnormal heart rhythms
		• Damage and scarring of lung tissue which may make you short of breath
		• A new cancer or leukemia resulting from this treatment.
		• Damage or scarring of urinary bladder tissue
		• Severe allergic reaction which can be life threatening with shortness of breath, low blood pressure, rapid heart rate chills and fever
		• Infertility which is the inability to have children

Risks and Side Effects Related to Etoposide Include Those Which Are:		
Likely	**Less Likely**	**Rare But Serious**

• Nausea and vomiting
• Hair loss
• A feeling of weakness or tiredness
• Fewer red and white blood cells and platelets in the blood
  ○ a low number of red blood cells can make you feel tired and weak
  ○ a low number of white blood cells can make it easier to get infections
  ○ a low number of platelets causes you to bruise and
	• Loss of appetite
	• Decreased blood pressure during the infusion which may require treatment
	• Rashes
	• Diarrhea
	• Pain in the abdomen
	• Mouth sores
	• Tingling sensation or loss of sensation in fingers or toes
	• A feeling of extreme tiredness or weakness
		• Damage to the liver
		• Severe allergic reaction which can be life threatening with shortness of breath, low blood pressure, rapid heart rate, chills and fever
		• A new cancer or leukemia resulting from this treatment
		• Severe rashes which can result in loss of skin and damage to mucous membranes
		• Absence or decrease

Risks and Side Effects Related to Etoposide Include Those Which Are:		
Likely	**Less Likely**	**Rare But Serious**
bleed more easily	• The finger or toe nails may loosen from their nail beds • Inflammation of the vein through which the medication was given • Chest pain	monthly periods which may be temporary or permanent and which may decrease the ability to have children • Damage to the heart muscle which may make you feel tired, weak, feel short of breath, and retain fluid

There also may be other side effects that we cannot predict. Many side effects go away shortly after the drugs are stopped, but in some cases side effects can be serious, long-lasting, or permanent. Other drugs may be given to make side effects less serious and uncomfortable.

C3. OTHER RISKS OF THIS RESEARCH STUDY

Risks of Blood Drawing

Risks associated with drawing blood are slight, but some risks include: pain, excessive bleeding, and bruising around the needle stick site, fainting or feeling lightheaded, infection (a slight risk any time the skin is broken), and multiple punctures to locate veins. If you do not have an indwelling venous catheter (i.e. an IV), a topical anesthetic cream (numbing cream/lotion) can be used to decrease the discomfort of blood drawing. The procedure will be performed with sterile preparation (clean the skin with alcohol or iodine wipes) at the site of the blood draw and a band aid will be applied at this site to prevent any additional bleeding.

Bone Marrow Examination Risks

The test may be painful. There is also a small risk of infection or bleeding. The pain normally lessens within minutes to hours.

C4. REPRODUCTIVE RISKS

Risks to Women Who Could Become Pregnant: The drugs in this study might affect a baby, before or after the baby is born. We do not know if the drugs cause harm to a baby, so we do not want anyone who might be pregnant to enter the study. You should not become pregnant or nurse a baby while in this study. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the study.

If you become pregnant or father a child during this study, contact your doctor immediately to discuss the requirements for pregnancy outcome follow-up.

Female subjects will be given instructions for discontinuation of study medication.

Risks of Fathering a Child: You should not father a baby while taking part in this study because it is unknown if the drugs in this study could affect a baby. If your partner is able to become pregnant, one or both of you must use some form of effective birth control. You must tell the study doctor right away if you think your partner is pregnant.

Birth Control Methods for all Subjects: Check with the study doctor about the birth control methods needed for this study and how long to use them. Some methods might not be good enough for this study. If you are having sex that could lead to pregnancy, you should use birth control while you are in this study. This may include:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Surgical sterilization (hysterectomy or tubal ligation)
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of diaphragm with condoms ("double barrier")
- Limiting sexual activity to a male partner who has had a vasectomy

You should continue using birth control for 2 months after stopping the study treatment.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We don't know if this study will help you. Your condition may get better but it could stay the same or even get worse. We hope the information from this study will help us remove MRD prior to going on to HCT but this is not guaranteed. Your cancer may not have any response to the therapy received while participating in this study.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. Some third party payers (insurance companies, HMOs, etc.) may not pay for hospitalization, treatments or procedures which are determined to be experimental or research related. The study has no plans to pay for medical treatment.

The health care costs during your participation in this study that are considered part of the standard treatment of your disease will be billed to your insurance or other third-party payer. This includes blood tests, hospitalizations, procedures that will be done, and medications. All costs not paid by your insurance will be your financial responsibility. Please ask about any expected added costs or insurance problems. Financial Counselors are available to discuss insurance, costs and other issues.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at *http://www.cancer.gov/clinicaltrials/learningabout.* You can print a copy of the Clinical Trials and Insurance Coverage information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy of Clinical Trials and Insurance Coverage.

D2. WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

There are no plans for you to receive payment for participating in this study.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. If you do not join this study, your doctor can discuss other healthcare choices with you. Most treatment plans have used drugs similar to those used in this protocol, although these drugs may be given in different combinations, and at different times. You can receive other combinations of chemotherapy without participating in this study.

As an alternative to this study, you may decide you don't want additional treatment for your relapsed leukemia. You will always receive medicines to help you feel more comfortable and deal with problems caused by your cancer or treatment whether you participate in this study or not.

Talk to your doctor about your choices before you decide if you will take part in this study.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important new information about the drugs used in this study that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D5. WHAT HAPPENS IF I AM HARMED BECAUSE I TOOK PART IN THE STUDY?

No funds have been set aside to pay any costs if you become ill or are harmed because of this study. If you think that you have become ill or were harmed because of this study, let the study doctors know right away by calling the Principal Investigator at your participating institution. The institutions and their responsible investigators are listed below. By signing this form, you do not give up your right to seek payment for harm you receive while participating in this study.

Institution	**Contact Information**
Children's Hospital of Wisconsin Milwaukee, WI	Dr. Michael Burke 414-955-4170

Froedtert Lutheran Memorial Hospital Milwaukee, WI	Ehab L. Atallah, MD 414-825-4600
University of Wisconsin, Madison Madison, WI	Neha J. Patel, MD 608-263-8554
Nationwide Children's Hospital Columbus, OH	Susan Vear, MD 614-722-3583

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If you have more questions about this study at any time, you can call the Principal Investigator at your participating institution at the same contact information given in the previous section (Section D5).
- If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To do this research study, we need your permission to collect and use some of your health information, or you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

The health information to be collected and used for this study is:

- Medical records of the care you receive for this study and the results of previous tests, exams, and procedures relating to the condition you are being treated for.

E2. Who will see the health information collected for this study?

The only MCW/Froedtert Hospital/Children's Hospital of Wisconsin employees allowed to handle your health information are those on the study team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

The study team may share your information with people who don't work at MCW/Froedtert Hospital/Children's Hospital of Wisconsin because they planned, pay for, or work with us on this study. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital/Children's Hospital of Wisconsin. For this study, we plan to share information with those doctors, researchers or government representatives working with us on this study at the institutions or companies listed here:

- U.S. Food and Drug Administration, Rockville, MD
- Multisite Coordinating Center - MCW/Froedtert Hospital Research/Children's Hospital of Wisconsin, Milwaukee, WI

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record or your applicable treating institution such as:

- Children's Hospital of Wisconsin
- Nationwide Children's Hospital
- University of Wisconsin, Madison, medical record.

As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different study without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study doctor about whether this could apply to you.

E4. How long will you keep the health information for this study?

If you sign this form, we plan to keep your information for 10 years after the research study ends and the study file is closed with the IRB in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the Principal Investigator at your treating institution. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

F1. FOR MORE INFORMATION ABOUT THE STUDY

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

You can look up this study by referring to the ClinicalTrials.gov number (NCT02349178) or by asking the study team for a printed copy.

CONSENT/ASSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Date or Date & Time: Time on subject's line is optional to include; if included in template, must be completed by each subject.

Child/Subject's Name *please print*	**Child/Subject's Signature**	**Date**
Parent's/Guardian's Name *please print*	**Parent's/Guardian's Signature**	**Date**
Name of Legally Authorized Representative (if applicable) *please print*	**Signature of Legally Authorized Representative**	**Date**
Name of Witness (if applicable) *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date**

*** Name of Person Discussing/ Obtaining Consent** *please print*	**Signature of Person Discussing/Obtaining Consent**	**Date**
** A member of the study team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. In all research study protocols the Principal Investigator is responsible and accountable for the study.*		

Name of Principal Investigator *please print* __ I participated in consent process __ I acknowledge enrollment of this subject into the study	**Signature of Principal Investigator**	**Date**