Children's Hospital Boston

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title:
Pediatric Myelodysplastic Syndrome and Bone Marrow Failure Disorder Registry and Tissue Repository

Principal Investigator:
Inga Hofmann, MD

Why is this research study being conducted; What is its purpose?

We are inviting you to participate in a research study. Research is a way of gaining new knowledge. A research subject is a person who is being studied by the researchers. Research studies include only patients (subjects) who choose to participate.

You are being asked to participate in this study because your doctors know or suspect that you might have a disorder called Myelodysplastic Syndrome (MDS) or a form of a bone marrow failure (BMF) disorder.

What is MDS?

Myelodysplastic syndrome (MDS) is a rare disease of the blood. It develops in the bone marrow, the soft, spongy center of the long bones that produces the three major blood cells (white cells, red cells and platelets). MDS occurs when the bone marrow does not properly produce sufficient numbers of healthy blood cells. In the normal bone marrow growth and development of blood cells is carefully controlled to produce the correct number of each type of blood cell to keep the body healthy. All blood cells are made from the start in the bone marrow from a single type of a cell called a stem cell. In MDS this process of maturation from a stem cell into a mature cell is disturbed. Sometimes the number of immature blood cells, called blasts, increases. As the disease progresses these blasts continue to increase and invade the bone marrow, making it impossible for the bone marrow to work effectively. Some cases of MDS (about one third) progress to leukemia, which is a cancer of the blood and bone marrow. Sometimes the blood cells produced in the bone marrow of patients with MDS also lose their ability to mature and function properly. Thus, overall, patients with MDS have varying degrees of bone marrow failure.

What is bone marrow failure?

Bone marrow failure (BMF) means that the body cannot produce enough of some or all of the blood cells that the body needs to stay healthy. Bone marrow failure can either be *inherited*, meaning that is genetic in origin, or can be *acquired* without an obvious genetic or inherited cause.

Inherited bone marrow failure syndromes include a group of hematopoietic (blood forming) stem cell disorders that can worsen over time and become life threatening. Patients with inherited bone marrow failure disorders are often at significantly higher risk of developing MDS or leukemia later in life.

Acquired bone marrow failure disorders are typically not clearly genetic (inherited) in origin and are usually not associated with a higher risk of cancer development. Acquired bone marrow failure can often mimic some forms of MDS. The most common form of acquired bone marrow failure is called Aplastic Anemia (AA). Aplastic anemia or bone marrow failure refers to conditions where the blood counts are very low because the bone marrow has become empty of blood forming cells.

In order to find out if you have MDS or an inherited or acquired BMF disorder, your primary physicians must examine the blood and bone marrow under the microscope. In addition several special tests on blood and bone marrow might be indicated to determine the exact diagnosis, which will be important as this information will help us decide what treatment is recommended.

In addition to collecting the blood and bone marrow samples that are needed to make a diagnosis of MDS or BMF, we are also interested in taking extra blood and bone marrow samples for research so we can learn more about those disorders. In addition we will collect medical information about your/your child's disease from your/your child's medical records or from your primary care provider. This information will include medical history, physical exam findings, pathology and other laboratory reports.

You may also be asked to donate a sample –cheek cells, blood, blood from inside the bones (bone marrow), and/or skin cells – to allow researchers to grow your cells in the laboratory. These cells may become immortalized, that is being changed so that they can grow forever in the laboratory. The researchers will use these cells created from your donated sample to try to learn more about the disease that is causing your blood problem. It is also hoped that this research will eventually help develop new treatments for the disease.

The purpose of this study is to answer the following questions in order to gain more knowledge about these rare disorders and develop better therapies in the future.

- How frequent are myelodysplastic syndromes (MDS) and its subtypes, and the various types of bone marrow failure (BMF) disorders in children and young adults?
- How frequent do chromosomal and genetic abnormalities occur in the bone marrow of patients with MDS or BMF disorders?
- How many children are cured from MDS or BMF disorders when undergoing hematopoietic stem cell transplantation (HSCT)?
- What is the outcome of patients with MDS or BMF disorders that receive other forms of therapy (other than HSCT)?

In addition, as mentioned, cell samples will be utilized to create a tissue repository for patients with MDS and BMF disorder to allow researchers to study these rare disorders in more detail in the future with the hope to identify potential new therapies.

Who is conducting this research study, and where is it being conducted?

The research study is currently a single site study with Children's Hospital Boston being the only site. Our goal is to expand this study to multiple other pediatric hospitals that will include other major pediatric centers around the country.

An institution that is supporting a research study either by giving money or supplying a drug is called the "sponsor." The sponsor of this protocol is the Division of Hematology/ Oncology at Children's Hospital, Boston. The Principal Investigator of this study is Dr. Inga Hofmann. We anticipate that we will be able to collect about 25-30 patients/year, which will lead to about 150 patients over the next several years at Children's Hospital Boston. However, in collaboration with other centers in the country we anticipate to collect about 50 patients per year in the future with the overall goal to have 250 patients participate over a 5-year time span.

How are individuals selected for this research study? How many will participate?

We will select men, women and children under the age of 35 with known or suspected MDS or an inherited or acquired BMF disorder. You/your child may have been identified as a potential participant for this research study by a doctor or care provider that you/your child met as part of your/your child's care in the Division of Hematology/Oncology at Children's Hospital Boston. Alternatively, you may have contacted us after seeing a notice regarding this study at Children's Hospital Boston or on a Children's Hospital Boston website, or by hearing about the study from other people you know.

We would like you to consider participating in our research. This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research subject. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study. We encourage you to take some time to think this over and to discuss it with other people and with your doctor and to ask questions now and at any time in the future.

What do I have to do if I am in this research study?

If you/your child chooses to participate in this study, we are asking to draw extra tubes of blood, obtain extra sample of your bone marrow and/or other tissue samples (such as buccal swabs, and/or skin biopsy) at the same time that samples are already being obtained for medical purposes to avoid extra blood draws and procedures.

Samples

If you take part in this study, we will obtain the following samples (marked with a checkmark by the investigator):

☐ Cheek cells by providing saliva through spitting in a tube (Oragene DNA collection kit) or brushing the inside of the cheek ("buccal swab")

☐ Blood taken from your vein (venipuncture)

__ Up to 1 teaspoon (ages under 2 years)

__ Up to 2 teaspoons (ages 2-11 years)

__ Up to 4 teaspoons (ages 12 years and above)

☐ Up to 2 teaspoons of bone marrow taken from inside the bone in your hip ("bone marrow").

☐ A skin sample, about half as wide (2mm) and half as deep as the eraser on the back of a pencil, usually taken from the same site as the bone marrow is taken or from the arm.

If you do <u>not</u> wish to have skin biopsy done on you or your child, please write "**NO**" next to the box and initial it. Please make it visible.

Samples from the oral mucosa (Oragene DNA collection kit) and/or the skin will be obtained to have additional "germline" tissue available that will function as a normal control to the diseased tissue we obtain from the blood and bone marrow. In some cases a skin biopsy will be indicated for clinical purposes to perform specialized testing

as part of your clinical work-up. If they are not needed for clinical purposes we will discuss with you if you/your child is willing to donate these additional samples.

The decision of which samples to obtain will in part depend on what procedures you will undergo in the future (such as blood draws, procedures involving anesthesia, bone marrow biopsies, etc) as part of your routine clinical care.

Medical and Demographic Information
If you take part in the study, we will obtain medical and demographic information such as diagnoses, family history of illnesses, medical record numbers, names and dates associated with your evaluations, symptoms and signs of disease, and therapies. We will also obtain laboratory test results, including:

- ☐ Blood counts and indices
- ☐ Chemistry tests _____
- ☐ Blood bank tests_____
- ☐ Viral serology testing _____
- ☐ Specialized testing for bone marrow failure disorders_____
- ☐ Bone marrow aspirate and biopsy results_____
- ☐ Cytogenetic and Fluorescent in situ hybridization (FISH) results from the bone marrow or ____
- ☐ Other _____

We will obtain the above information mostly from your care provider in the Division of Hematology/Oncology and from your medical records. We will access your medical record or contact your care provider for research purposes. In general we will not need to contact you for research purposes. However, if we do so it will be no more than twice per year.

We will collect your medical information from the date ___ /___/_____ onward, or until you terminate participation in the study.

Participation in this research study will not require any additional study visits besides your routine clinical care visits with your Hematologist/Oncologist or HSCT physician. We plan to follow each individual patient for up to 25 years in order to learn about the long-term outcomes of MDS and BMF disorders.

The study does not concern the treatment of you/your child's disease and therefore does not include a therapeutic trial (administration of experimental therapies). This research study only concerns the diagnosis and course of your/your child's disease and future laboratory research to learn more about MDS and BMF disorders.

What are the risks of this research study? What could go wrong?

Physical risks
-There is no risk beyond the procedure itself for donation of additional blood or blood from inside the bone (bone marrow) taken during a regular medical procedure. Furthermore, there is no additional risk for donation of extra remaining blood or bone marrow samples, which were collected as part of medical care and are destined to be thrown away once clinical testing is completed.

-There is a small risk of minimal discomfort for a brief moment during donation of cheek cells.
-There is no risk involved in the donation of oral saliva by spitting in a tube.
- There is a likely risk of pain while a skin sample is being taken for research purposes, when it is a procedure being done in the office (ages 18 years and older only). This pain will be lessened by pain medication given in the skin. There are the small risks of pain, bleeding and infection after the skin sample is taken that will be lessened by pain medication given in the skin and by performing the procedure under clean (sterile) conditions. There is the likely risk of getting a scar at the site where the skin sample is taken. We will try to take the skin sample from the same site as the bone marrow biopsy is taken (hip) to limit additional scar formation. A minor scar will occur from the bone marrow procedure alone even if obtained just for clinical reasons. If the skin biopsy is taken from a place like the upper arm or forearm a small scar might occur. Therefore, whenever possible we will obtain the skin biopsy form a bone marrow procedure site.

Emotional risks
There is potential for emotional and psychological discomfort for people donating cells to be used for research. Patients uncomfortable with the thought of their cells being used for research purposes should not participate in the study. There is the potential for emotional and psychological discomfort when we are asking you about your own or your family members' medical problems. Patients have the right to refuse to discuss details of their own or their family members' medical problems during this study.

Privacy risks
Your privacy may be at risk when members of the research staff contact you by phone or by mail to discuss your participation in this study. We will try to protect your privacy and decrease the possibility of violating your privacy by discussing this study with you from locations that help maintain privacy (such as a private office), and by keeping the details of your private medical information out of e-mail or regular mail messages to you as much as possible.

There are no adverse consequences of a participant's decision to withdraw from the research at any time.

What are the benefits of this research study?

There are no direct benefits to you as a participant in this research study. However, by studying the clinical data we collect from patients and by studying the cells you donate for research, we hope to better understand rare disorders such as MDS and BMF. In addition we hope to gain greater knowledge of the gene problem that we think is causing your blood disorder.

Body tissues are made up of cells. Cells contain DNA, which is your unique genetic material that carries the instructions for your body's development and function. Many diseases can result from changes in a person's genetic material that causes cells to not work properly. Currently, researchers and doctors know some of the genetic changes that can cause disease, but they do not know all of the genetic changes that can cause disease. Therefore, we would like to study the genetic material from you. By combining this information with information from your medical records, it may be possible to identify the genetic changes that are associated with your particular type of disease. We will perform this same process with hundreds of other people who have agreed to participate in this research project. Since we also will combine genetic information with information from medical

records, such as different people's responses to treatments, this project could lead to more knowledge about why certain people respond differently to a treatment.

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

____ Please contact me or my health care provider if results become available in the future:

Physician's name: _____
Phone: _____
Address: _____

_____ Please do NOT contact me (check and initial)

During the research we may collect different samples from you/your child such as blood, bone marrow, buccal swab material, or skin biopsy material, as described in the informed consent document. It is possible that what we learn or create from these samples, or the samples themselves, may be made available to other hospitals, and universities, for further research. The research may also lead to new products, research tools, or inventions that are patented. If these lead to payments to Children's Hospital Boston, the money the Hospital receives will be used to support biomedical research or provide healthcare to our patients, except that people who make the discoveries may receive some portion of the amount. We believe that devoting such payments to research and health care is the best way to benefit patients as whole, so we do not transfer those payments to research participants.

Are there costs associated with this research study? Will I receive any payments?

Taking part in this research study will not lead to added costs to you or your insurance company. Children's Hospital Boston will pay for the materials and procedures to obtain and process the samples you donate as part of this study.

You will be reimbursed for parking expenses for your visits to Children's Hospital Boston during which you participate in this study. There are no other monetary benefits or compensation to you as a participant in this research study.

In the event of an injury resulting directly from your participation in this research study, medical treatment will be provided if the injury is reported in a timely manner. Provision of such medical care does not imply any negligence or other wrongdoing on the part of the Hospital or any of the physicians or other personnel involved in the study. Where applicable, the Hospital reserves the right to seek payment from third-party payers for any medical care or services rendered. The Hospital has no program to provide you with any additional compensation as a result of any such injuries.

What will happen with the information obtained as part of this research study? What about confidentiality?

Provision of samples and medical and demographic information as part of this study poses risks to the confidentiality of your information. We will maintain confidentiality of your data and samples by (1) stripping the sample of identifying information and providing only the age in years and gender and non-identifying medical information of the patient to researchers using the samples; and (2) maintaining any additional demographic and medical information in a locked cabinet to which only the study investigators and Project Manager have access. Although the tissue sample provided to the researchers will be stripped of patient identifiers, the genetic content of these cells and stem cells derived from them could theoretically be used (though with enormous difficulty) to identify you. Patients uncomfortable with the thought that their donated samples could be traced back to them should not participate in this study.

You should also be aware that there might be social and economic disadvantages, which can be associated with the gathering of genetic information. You should understand that our testing might find an inherited defective gene, which puts you or a relative at risk for a genetic disorder in the future. Genetic information divulged to the wrong source, could affect you and your family if an insurance company or employer acquired this genetic information. We will do our best to keep all information confidential and, only with your permission, would we make this information available to others. A copy of this consent form will not be placed in your medical record. The results of the tests performed for research purposes will not be placed in your medical record. In this manner it will be unlikely that others within the hospital, an insurance company or employer would ever learn of such results.

We have a Certificate of Confidentiality (CC) from the US government. It adds special protection for research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. Still, we may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, and the government may see your information if it audits us. This Certificate does not mean the government approves or disapproves of our project. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: if the researchers are concerned that you may be suicidal (thinking about killing yourself) or otherwise at immediate risk for seriously harming yourself or others they will need to notify your primary care provider or counselor and/or involve your parents or guardian according to standard clinic practice or if, during your participation in this study, we learn about serious harm to you or someone else, such as child abuse, we will

take steps to protect you or other people, including notifying the Department of Social Services or other authorities.

A copy of this consent form will be placed in you/your child's medical record.
Medical information collected during this study will become part of your/your child's hospital record, if the information is determined to be pertinent to the care you/your child receive at Children's Hospital. Medical records are considered permanent record, therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at Children's Hospital and may be reviewed by Hospital staff in their course of carrying out their responsibilities, however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your/your child's medical record may not be given to anyone unaffiliated with Children's Hospital in a way that could identify you/your child without written consent, except as required or permitted by law. Information collected during the study that does not become part of your/your child's medical record will be stored in separate research files maintained by the investigator. These research records will not be made available to any individuals who are not part of the research team unless you so request or as required by law. If you/your child withdraw from the research study, information that has already been collected will become part of the research data, however, you/your child will not be identified.

The results of the genetic tests will be placed in your/your child's medical record. This will only be the case for tests, which are CLIA approved and indicated as part of your clinical care (such as specialist testing for inherited bone marrow failure disorders). In this manner others, including an insurance company or employer may learn of such results.

If I do not want to take part in this research study, what are the other choices?

Providing us with you/your child's medical history and laboratory data as well as donating your tissue samples – blood, bone marrow, cheek cells, and/or skin - for this research project is completely voluntary. You have the right to agree or to refuse to provide your cells for this study. Your current or future medical care and your relationship with Children's Hospital Boston will not change in any way whether you agree, or refuse to participate in this study.

What are my rights as a research participant?

You may terminate your participation in this study at any time and for any reason. You can stop participating in this study at any time by contacting your primary care physician that referred you or by contacting the study center directly. You may also discuss this decision with the principal investigator of this study, Dr. Inga Hofmann at (617) 919-3422. Once you decide to withdraw from the study, no further samples will be collected, no further testing will be done on samples we have already obtained from you, and any stored samples will be discarded. Also, we will not collect any new information regarding your disease or your treatment. However, results obtained prior to your withdrawal from the study will be maintained, your privacy will be preserved. Your current or future medical care and your relationship with Children's Hospital Boston will not change in any way, whether you continue to participate in or withdraw from this research project.

Are there other things I should know about?

At the completion of this study, we would like to store any remaining sample for possible future use. The remaining samples may be stored indefinitely and may be used for future studies of genetic causes of your disease.

The samples will be stored in the Division of Hematology/Oncology at Children's Hospital Boston. Your sample will be given a unique identification number and stored without your name or other identifiers. Only the investigator will have a list to know which sample is linked to which patient and this list will be kept confidential in a secure location. If the investigator distributes these samples to other individuals who have an interest in the causes of the disease, it will be released with the unique identifier without any names or medical record numbers. If at any time you would like to have the sample removed from our storage, please let us know and it will be transferred or destroyed according to your wishes. However, please be aware that any samples that have already been distributed to other investigators will most likely not be destroyed.

Why would I be taken off the study early?

There are no anticipated circumstances under which your/your child's participation will be terminated by the investigator without regard to the participant's consent.

What information do I need to know about the Health Insurance Portability and Accountability Act (HIPAA)?

During this research, information about your or your child's health will be collected. In general, under federal law, information about patients is private, but there are exceptions and you should know who will have access to this information and might see it. Researchers may be collecting information about you or your child from medical records. They may also learn things from procedures that are part of the research itself such as tests, office visits, questionnaires and interviews.

The following people will be able to see this information:

- Medical and research staff at Children's Hospital, including people listed on your informed consent.
- Medical staff that are directly involved in your care that is related to the research or arise from it.
- People, who oversee, advise or conduct research at Children's Hospital, and people who oversee or evaluate research and care, including the Committee on Clinical Investigation, staff working on quality improvement, and other clinicians and administrative staff of Children's Hospital.
- People from agencies and organizations that provide independent accreditation and oversight of research.
- Sponsors or others involved in funding the research.
- Federal agencies that oversee or review research information.
- Government agencies and sponsors.
- If some law or court requires us to share the information, we would have to follow that law or final ruling.

You/your child should be aware that the federal privacy rule does not cover all of these possible uses. This means that once some of the above mentioned users receive your/your child's health information they do not have to follow the same rules. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Children's Hospital Privacy Officer at 617-355-5502.

There is no set time for destroying this information and no time limit for its use. Researchers continue to analyze data for many years and it is not possible to know when they will be done.

You/your child do not have to sign this form. If the form is not signed, however, you won't be able to participate in the study. Not signing will not affect your care or your child's care at Children's Hospital in any way now or in the future. Also, there will be no penalty or loss of benefits if you choose not to sign and participate.

You/your child also have the right to withdraw from this study at any time. You have the right to end your permission for Children's Hospital to use or share the protected information about you or your child that was collected as part of the research.

Researchers may also continue to use information already collected to protect the integrity of the study. This means that your withdrawal won't make the whole study useless. Once you remove your permission and you or your child is no longer in the study, no more private health information will be collected. If you wish to withdraw you will need to do so in writing. If you/your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information.

Although there are some legal limitations, you/your child have the right to get protected information resulting from this research that relates to your treatment or to payments. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 617-355-5502. If you have questions, please be sure to ask for answers.

Research at Children's Hospital: Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org

Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's Hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions or concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30and 5:00.

CONSENT/AUTHORIZATION:

***If the child to be involved in this research study is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.**

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call …	At …	If I have questions or concerns about …
Investigator: Dr. Inga Hofmann	Phone: **617-919-3422** Pager:**617-355-7243 Pager #1238** mds@childrens.harvard.edu	▪ General questions about the study. ▪ Research-related injuries or emergencies. ▪ Any research-related concerns or complaints.
Study Contact: Grace Yoon NNP	Phone:**617-355-9148** Pager:**617-355-7243 Pager # 2258** grace.yoon@childrens.harvard.edu	▪ General questions about the study. ▪ Research-related injuries or emergencies. ▪ Any research-related concerns or complaints.

Office of Clinical Investigations Phone: **617-355-7052**

- Rights of a research subject.
- Use of protected health information.
- Compensation in event of research-related injury
- Any research-related concerns or complaints.
- If investigator/study contact cannot be reached.
- If I want to speak with someone other than the Investigator, Study Contact or research staff.

I have been satisfactorily informed of the above-described procedure with its possible risks and benefits. I have been provided with the applicable Privacy Rule provisions under the Health Insurance Portability and Accountability Act. I give permission for my/my child's participation in this study and for use of the associated protected health information as described above.

I understand that participation in this study is voluntary. If I refuse to participate or choose to drop out of the study at any time, I understand there will be no penalty or loss of benefits to which I am otherwise entitled, and this decision will not affect present or future care by the doctors or the hospital. I am signing this consent form before participating in any research activities. I have been given a copy of this form.

☒ _____ _____ _____

Date (MM/DD/YEAR) *If subject less than 18yrs:* Signature of **Parent or Guardian** or, *If subject 18yrs or older:* Signature of **Adult Participant** Relationship to child

☒ _____ _____

Date (MM/DD/YEAR) Signature of **Child/Adolescent Participant**

☒ If child/adolescent's assent **not** obtained above, please specify why (*e.g. too young, subject sedated*):

_____

INVESTIGATOR'S AND/OR ASSOCIATE'S STATEMENT:

I have fully explained to all involved parties (participant/parent/guardian as applicable) the nature and purpose of the above-described procedures and the risks involved in its performance. I have provided the subject/family with the Privacy Rule if requested. I have answered and will answer all questions to the best of my ability. I will inform the participant of any changes in the procedures or the risks and benefits if any should occur during or after the course of the study. I have given a copy of the consent/ authorization form to the subject/family.

☒ _____ _____

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

WITNESS SIGNATURE REQUIRED BELOW ONLY IF: (check which one applies)

- ☐ the consent document needs to be read to subject or legal representative **or**
- ☐ communication impairments limit the subject's ability to clearly express consent **or**
- ☐ required by sponsor/CCI.
- ☐ other reason: please specify _____

I confirm that the information in this consent form was accurately explained to, and understood by the subject or legally authorized representative, and that informed consent was given freely.

☒ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**