**Informed Consent Form**

**Medical University of South Carolina**
**CONSENT TO BE A RESEARCH SUBJECT**

If participants include those under 18 years of age: 1) The subject's parent or legal guardian will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides his/her assent. 3) In statements below, the word "you" refers to your child or adolescent who is being asked to participate in the study.

**TITLE OF RESEARCH:** The effect of a collaborative art therapy and physical therapy intervention on children undergoing a hematopoietic cell transplant: a randomized clinical trial.

## SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part.

The purpose of this study is to compare the effect of a combination of art therapy (AT) and physical therapy (PT) to PT only in children undergoing hematopoietic cell transplant (HCT). Each child will receive daily AT and PT or only PT for 5 days per week for 2 weeks. These sessions will begin approximately on day 15 following the transplant. Prior to starting the sessions and following 2-weeks of sessions, we will measure your self-care and mobility skills. During each session, we will measure your heart rate variability (i.e., time between heart beats) using a small monitor on the chest (about the size of a quarter), walking distance using an accelerometer (similar to wearing a watch), and your self-reported happiness and excitability. Although results cannot be guaranteed, we expect each group will benefit and demonstrate improvements in emotional state, self-care, and mobility skills.

There are risks associated with participation in the research study which include:

- As with any AT session, the primary risks are recognizing and expressing emotions (i.e., fear, anxiety) associated with treatment.
- The PT sessions, designed to enhance movement/exercise, endurance, strength, and independence in self-care and walking, may cause temporary discomfort similar to what is experienced when anyone exercises.
- Although your name will be replaced with a number to protect your identity (coded data), there is a possibility that your confidentiality could be compromised.

An alternative to this study's interventions is not to participate in the research project and receive normal routine care.

If you are interested in learning more about this study, please continue to read below.

## A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this study involving research is to examine and compare the effects of either art therapy (AT) combined with physical therapy (PT) to only PT treatment in children following hematopoietic cell transplant (HCT). Your child is being asked to participate in this study because he or she has had an HCT. The study is being done only at MUSC Shawn Jenkins Children's Hospital. This study plans to enroll 20 children who have undergone HCT. A grant from the National Endowment of the Arts is sponsoring this study. Portions of the principal investigator and his/her research team's salaries will be paid by this grant.

## B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will need to be in the hospital, have undergone a recent hematopoietic cell transplant (HCT), and be between the ages of 3 and 18 years.
2. You will be randomly assigned to one of two groups, like flipping a coin. The groups will be A and B.
3. If you are assigned to Group A, you will receive art therapy (AT) (45 minutes) and (physical therapy) PT (30 minutes) one time a day for 2 weeks.

   If you are assigned to Group B, you will receive PT (30 minutes) one time a day for 2 weeks.
4. Before participating in this study's AT and/or PT, your mobility and self-care skills will be measured by asking questions about your ability to complete such activities as walking and dressing. Your mobility will also be measured using the 6-Minute Walk Test, in which we will measure how many feet you can walk in 6 minutes. These measurements will take approximately 30 minutes to complete and will done by a licensed physical or occupational therapist.
5. Before each session of AT and/or PT, a heart rate variability monitor and accelerometer will be placed on your chest and wrist. The heart rate variability monitor is a little larger than a quarter and is applied using sticky electrodes. The accelerometer is similar to an iWatch. These will be removed immediately after each session. You will also report your happiness, calmness, and control before and after each session.
6. If you are in Group A, you will receive 45-minutes of AT with an art therapist followed by PT for 30-minutes with a physical therapist.

   If you are in Group B, you will PT for 30-minutes with a physical therapist.
7. You may withdraw from this study at any time.

## C. DURATION

Participation in the study will take 10 visits over a period of 2 weeks. This study will begin on approximately day 15 following hematopoietic cell transplant (HCT).

## D. RISKS AND DISCOMFORTS

The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

Following hematopoietic cell transplant (HCT), you may more easily fatigue and feel fearful. Although the purpose of this study is to help manage these symptoms, movement activities carried out during art therapy (AT) and/or physical therapy (PT) may increase your fatigue and fear.

As with an increase in movement or activity, there are associated risks of falls. Prior to each day's intervention session, the art and physical therapists will discuss your medical stability to ensure you are safe to participate.

All study materials associated with you will use an assigned number rather than your name and data collected from these materials will be stored on secure and password protected computer and electronic data collection system; however, there is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

## E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record We will make every effort to keep confidential all research information in the medical record that identifies you to the extent allowed by law.

## F. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

Whether or not there is direct benefit to you from participating in this study, it is hoped that the information gained from the study will help in the treatment of future children undergoing HCT.

## G. COSTS

There will be no additional cost to you for procedures required in this research study. All routine clinical care that you would have undergone without participation in the study, including testing and procedures, will be billed to you/your insurance company. All study-related tests and procedures will be paid for by the Sponsor.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

## H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

## I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is one to two times per week.

## J. DATA SHARING

Information about your child (including your identifiable private information and/or any identifiable biospecimens) will have all of your identifiers removed before being used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

## K. DISCLOSURE OF RESULTS

Clinically relevant research results will be shared through publications. Participants are welcome to contact the principal investigator following completion of the study to obtain a copy of those publications.

## L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your child's study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;

- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child;
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

## M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

## N. CLINICAL TRIALS.GOV

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.

## O. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

### Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact **Cindy Dodds, PT, PhD at 843-792-5731**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about

your rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

*If you wish to participate, you should sign below.*

_____ _____
Signature of Person Obtaining Consent Date *Name of Participant

Participant's Personal Representative (if applicable):

_____
Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*
**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

*12-18 years of age:
"My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____

MUSC
Medical University of South Carolina

# NOTICE OF PRIVACY PRACTICES

## MUSC Organized Health Care Arrangement (OHCA)

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

**UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)**
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

**OUR PLEDGE REGARDING YOUR HEALTH INFORMATION**
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

**HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –**

**A. The following uses do NOT require your authorization, except where required by SC law:**
**1. For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
**2. To obtain payment**. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
**3. For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
**4. Business Associates.** Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
**5. For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
**6. Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
**7. Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
**8. Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.
**9. Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
**10. Military and Veterans**. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
**11. Uses and disclosures about patients who have died.** We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
**12. For purposes of organ donation.** As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
**13. Research.** We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
**14. To avoid harm.** In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
**15. For workers compensation purposes.** We may release your PHI to comply with workers compensation laws.
**16. Marketing.** We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
**17. Fundraising activities.** We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
**18. Appointment reminders and health-related benefits and services.** We may contact you with a reminder that you have an appointment.
**19. Disaster Relief Efforts**. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
**Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.**

**B. You may object to the following uses of PHI:**
**1. Inpatient hospital directories.** Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

**2. Information shared with family, friends or others.** Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
**3. Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

**C. Your prior written authorization is required (to release your PHI) in the following situations:**
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
**1.** Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
**2.** Mental Health Records unless permitted under an exception in section A.
**3**. Substance Use Disorder Treatment records unless permitted under an exception in section A.
**4.** Any circumstance where we seek to sell your information.

## WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
**A. The Right to Request Limits on How We Use and Release Your PHI.** You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
**B. The Right to Choose How We Communicate PHI with You.** You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
**C. The Right to See and Get Copies of Your PHI.** You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
**D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI.** This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
**E. The Right to Amend Your PHI.** If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
**F. The Right to Receive a Paper or Electronic Copy of This Notice:** You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
**G. The Right to Revoke an Authorization.** If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
**H. The Right to be Notified of a Breach.** If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

## HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

## HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

## PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

## CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

## EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.