Informed Consent for Clinical Research
MedStar Health Research Institute/Georgetown University Medical Center/Hackensack University Medical Center/Northwestern University
FOR REVIEW WITH RESEARCH STAFF

INSTITUTION: **Georgetown University Medical Center (GUMC)**
Hackensack University Medical Center (HUMC)
Northwestern University (NU)

INVESTIGATORS: **Christine Rini, PhD**
Kristi Graves, PhD
Scott Rowley, MD

INTRODUCTION

You are invited to consider taking part in a research study. The study is called the WISE (Writing for Insight, Strength, and Ease) Study. Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to everyone who takes part in our studies:

(a) Taking part in the study is entirely voluntary;

(b) You may not benefit personally from taking part in the study, but you may help us gain knowledge that will benefit other people;

(c) You may decline to take part or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing (risking) your access to care, treatment, and health services unrelated to the research.

Below we discuss:

- The purpose and nature of the study,
- Possible benefits, risks, and discomforts,
- Other options,
- Your rights as a participant, and
- Other information about the study.

We will provide you with any new information that is discovered, at any time during the research that might affect your decision to take part in or remain in the study. We urge you to ask the staff explaining the study any questions you have about this study. We also urge you to take whatever time you need to discuss the study with your physician, hospital personnel, and your family and friends. The decision to take part in the study, or not, is yours.

If you decide to take part in the study, please sign and date where indicated at the end of this form. The investigators (persons in charge of this research study) are Dr. Christine Rini at Northwestern University (NU), Dr. Scott Rowley at Hackensack University Medical Center (HUMC), and Dr. Kristi Graves at Georgetown University Medical Center (GUMC). The HUMC/GUMC Sub-Investigators include Dr. Michele Donato, Dr. Pashna Munshi, Dr. Themba Nyirenda, and Dr. George Luta.

The research is being sponsored by the National Cancer Institute (NCI) of the National Institutes of Health (NIH). NIH/NCI is called the sponsor. Northwestern University, Hackensack University Medical Center, and Georgetown University are being paid by NIH/NCI to conduct this study with Dr. Christine Rini and Dr. Kristi Graves as the primary investigators.

WHY IS THE STUDY BEING DONE?

This research is being done because many people report physical and emotional symptoms when they have a stem cell or bone marrow transplant. Research shows that certain ways of writing can reduce these kinds of symptoms. The purpose of this study is to compare the effects of two different types of writing to see how each one affects patient symptoms and quality of life.

You are being asked to take part in this study because you have been diagnosed with cancer, are over the age of 18, can read and speak English, have telephone service, and are scheduled for an allogeneic or autologous transplant at the John Theurer Cancer Center at Hackensack University Medical Center, Robert H. Lurie Comprehensive Cancer Center at Northwestern University or Georgetown Lombardi Comprehensive Cancer Center.

You may not participate in this study if any of the following apply to you:

- You are currently taking part in a study that uses a behavioral intervention to improve your symptoms or quality of life. However, you may be using medications or medical procedures to improve your symptoms or quality of life.
- You have problems with thinking, mental health, or reading that make it difficult for you to give informed consent or do the study procedures
- You are having a tandem transplant (two transplants, planned to happen one after the other) and are now completing the first of these planned transplants

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 335 participants will take part in this study. Up to 300 participants will be recruited at John Theurer Cancer Center, up to 60 participants will be recruited at Georgetown Lombardi Comprehensive Cancer Center, and up to 100 participants will be recruited at Robert H. Lurie Comprehensive Cancer Center.

WHAT IS INVOLVED IN THE STUDY?

If you decide to take part in this study, you will do the following things:

1. At the beginning of the study you will complete a 45 minute baseline phone interview that includes questions about your background; your thoughts, feelings, and behaviors; and how you feel emotionally and physically.
2. You will complete four writing sessions in which you write about your transplant experiences. They happen with the following timing.
    a. Writing session 1: Very soon after you enter the hospital for transplant.
    b. Writing session 2: Approximately three days after you leave the hospital.
    c. Writing session 3: Two weeks after writing session 2.
    d. Writing session 4: One week after writing session 3.

    For the writing sessions, the study interviewer will call you and ask you some questions about how you feel. Then the interviewer will give you writing instructions and you will write for 20 minutes. After 20 minutes, the interviewer will call you back and ask you questions about how you feel and about your writing. The timing of all interviews and writing sessions will be flexible to accommodate your medical and life events.
3. You will complete six more phone interviews to help us understand how you are doing during and after your transplant. Here is when they will happen:
    a. About a week after your transplant (at "nadir," when your blood counts are low) you will do a phone interview that will last about 15 minutes
    b. About 2 weeks after your transplant (at "engraftment"), you will do a phone interview that will last about 15 minutes
    c. One week after writing session 4, you will do a "follow-up" phone interview that will last 30 to 45 minutes.
    d. You will then do three more of these 30 to 45-minute follow-up phone interviews. They will happen 3 months, 6 months, and 12 months after your last writing session.

Before you start writing, you will be "randomized" into one of two writing groups. Both groups will write about their transplant experience. However, the groups will receive different writing instructions. Randomization means that you are put into a group by chance. It is like flipping a coin. A computer is used to assign you to a group. Neither you nor the researchers choose what group you will be in. You will have an equal chance of being placed in either group. The interviewer who helps you complete the writing will know what group you are in, but neither you nor the interviewer doing the phone interviews will know what group you are in.

An optional part of the study is that we would like to audio record the parts of the study we conduct over the phone so that we have an accurate record of the discussion and for quality control, so we can make sure the staff is following procedures. In those audio recordings we would not use your name or other identifying information. If you do not want to be audio recorded, you do not have to agree to it. You can still be in the study.

_____ OK to audio record me during the study
_____ Not OK to audio record me during the study

If you take part in this study, you will also do whatever procedures are part of your regular care. These procedures may be done even if you do not join the study. They include allogeneic or autologous transplant, follow-up treatment, and care with physicians and a clinical team (as needed).

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 13 months. Most of the study procedures happen in the first few months. After the last writing session, researchers will follow up with you four times (1 week later, 3 months later, 6 months later, 12 months later).

You can stop participating in the study at any time. If you stop participating, it will not affect your medical care. If you decide to stop participating in the study, we encourage you to talk to the researcher.

This is a minimal risk study. There are no risks with any sudden withdrawal from the study.

If funding is stopped, the study may end and subsequently your participation in the study may end.

The investigators, physicians or sponsors may stop the study or take you out of the study at any time if they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

An optional part of the study is that we may want to contact you after this study is over, for instance, if we do a follow-up study or if we do a different study that we think you might be eligible to take part in. You do not have to agree to allow us to contact you after the study is over. If you do not want us to contact you after the study is over, you can still be in this study.

_____ OK to contact me after the study is over
_____ Not OK to contact me after the study is over

WHAT ARE THE RISKS OF THE STUDY?

This is a minimal risk study. We expect that the chances you will experience harm or discomfort in this study, and the severity of any harm and discomfort, are not greater than you would have in daily life or during routine physical or psychological tests.

There are no physical risks involved in taking part in this study. There is some risk of psychological distress due to study questions about your personal transplant experience and the writing sessions. However, because study questions were chosen to reflect what are likely to be existing concerns for you, the study is not expected to make you more distressed. You are free not to answer any question that makes you feel uncomfortable. If you or your writing show signs of psychological distress, our team may refer you to a trained professional.

In any research study there is the risk that your information could be learned by others. We take a number of steps to protect the confidentiality of the information you give us in the study.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You may not directly benefit from taking part in the study. However, people have often reported that discussing their transplant experience with a supportive interviewer decreases their distress. Also, people who have done the writing often report that it is a positive experience. Even if you do not benefit personally, your participation and the information you provide will hopefully increase our knowledge and teach us how to help people reduce their symptoms during and after transplant.

WHAT OTHER OPTIONS ARE THERE?

Whether or not you take part in this study, you will receive care to manage your symptoms and keep you comfortable. The alternative to participation is not to participate in this research. If you refuse to participate, it will not affect your medical care.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institutions conducting this study, organizations that may request to inspect and/or copy your research and medical records for quality assurance, data analysis and other research related and operational or administrative purposes, include groups such as:

The National Institute of Health, the National Cancer Institute, MedStar Health Research Institute, Georgetown University, Georgetown University Hospital, Hackensack University Medical Center, Northwestern University, MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB), Hackensack

University Medical Center IRB, Northwestern University IRB, and federal research oversight agencies. Please note that administrative personnel involved in processing your payment for participation, described below, will be aware of your identity.

Interviewers will also be aware of your identity. However, survey responses will be entered directly into a software program. As backup, interviewers may use paper surveys to record your responses. We will file those paper surveys by confidential study identification (ID) numbers. They will not include your name or any other information that can be used to identify you.

DATA SECURITY

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage:

- We will store your information on a secure server that only our study staff can access.
- We will store your name and other identifying information separately from your writing, your answers to study interview questions, and audio recordings of study interviews.
- Computer files with your writing, your answers to study interview questions, and audio recordings of study interviews will not be stored with your name or any other identifying information. Instead, we will use a confidential study ID number.
- Any data transferred between Georgetown Lombardi Comprehensive Cancer Center, Robert. H Lurie Comprehensive Cancer Center at Northwestern University, and John Theurer Cancer Center at Hackensack University Medical Center will be transferred using secure data transfer protocols.
- We will not store any information that could identify you on laptop computers or other mobile computing hardware.
- Computers used to access study data will be protected by a username and password.

WHAT ARE THE COSTS?

Study participants will not have to pay to take part in the study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for Georgetown University Medical Center, MedStar Health Research Institute, Hackensack University Medical Center, and Northwestern University are as follows:

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third party payer (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, MedStar Health Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness.

PAYMENT FOR PARTICIPATION

Participants will be paid $25 after completing the initial interview and after each follow-up interview, for a total of up to $125 if you complete all parts of the study.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

If you are injured as a direct result of your participation in this study, you may seek medical attention at the medical provider of your choice. However, you and/or your insurance company/third party payer will be billed for all routine medical, diagnostic, laboratory and pharmaceutical costs associated with the treatment of your illness or injury. You will be responsible for any deductibles or co-payments that would normally be associated with your insurance coverage. There will be no monetary compensation by Northwestern University, Hackensack Meridian Health, or Georgetown University Medical Center.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected nor will your relations with your physicians, other personnel and the hospital or university. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- Personal information: Name, address, date of birth, medical record number, phone numbers, email addresses, audio recordings
- Dates: Hospital admission and discharge, transplant date, follow-up appointments, and dates of selected medical events
- Results: Medical information related to diagnosis, disease stage, type of transplant, treatments, laboratory tests, physical exams, medications, comorbid conditions, complications, and symptoms
- Notes: Reported by clinical team about symptoms, complications, adverse events, or relapse

Once we have the health information listed above, we may share some of this information with other study sites: (Northwestern University, Georgetown University Medical Center, Hackensack University Medical Center), National Cancer Institute (NCI) of the National Institutes of Health (NIH).

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law, Georgetown University policy, MedStar Health policy, Hackensack University Medical Center policy, or Northwestern University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Georgetown University, MedStar Health, Hackensack University Medical Center, and Northwestern University workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB) Office and its agents, and members of the Institutional Review Board.
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Other Georgetown University and MedStar Health research centers, and Georgetown University, MedStar Health, Hackensack University Medical Center, and Northwestern University contractors who are also working on the study.
- National Cancer Institute (NCI) of the National Institutes of Health (NIH), who is sponsoring the study, and that company's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the conclusion of the study. After the expiration date, we may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless the research team obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

NEW FINDINGS

Throughout the study, we will tell you about new information that may affect your interest in remaining in the study.

CLINICALTRIALS.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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Kristi Graves at 202-687-1591 (at Georgetown Lombardi Comprehensive Cancer Center) or Dr. Christine Rini at 312-503-7715 (at Northwestern University). Be sure to inform them of your participation in this study.

For questions about your rights as a research participant, contact the MedStar Health Research Institute-Georgetown University Institutional Review Board at:

Address: Georgetown University Medical Center
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Telephone: (202) 687-1506