MAYO CLINIC

Name and Clinic Number

Approval Date: **November 6, 2018**
Not to be used after: **November 5, 2019**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Along the Path: Support after hematopoietic stem cell transplantation (HCT)

IRB#: 17-007602

Principal Investigator: Nandita Khera, M.D and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Nandita Khera **Study Team Contact:** Dr. Sunny Kim	**Phone:** (480) 342-3047 **Phone:** (602) 496-6789 **Institution Name and Address:** Mayo Clinic Hospital 5777 East Mayo Boulevard Phoenix, AZ 85054	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Arizona:** (800) 603-0558	▪ Billing or insurance related to this research study

1. Why are you being asked to take part in this research study?

You are being asked to take part in this study because you are a patient undergoing hematopoietic stem cell transplantation (HCT), and you may experience some level of emotional distress related to cancer treatment and transplantation.

The plan is to include 110 patient-caregiver teams for a total of 220 subjects in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of the study is to learn about patients and caregivers who have recently undergone transplant for hematopoietic cell malignancies. Research has shown that a web-based video intervention may be used as a therapeutic or education tool, suggesting that viewing HCT-related videos can have beneficial effects on patients' and caregivers' psychosocial wellbeing. We will use the information from this study to help us evaluate the use of this intervention to improve psychosocial well-being among HCT patients and caregivers.

3. Information you should know

Who is Funding the Study?

The National Institutes of Health (National Cancer Institute) will fund this study.

4. How long will you be in this research study?

Your time of participating in this study will be a 4-week series of web-based video intervention, and two visits before and after the interventions that is approximately 20-30 minutes long, and then again 3 months later to complete a smaller set of measures for the last time. Some subjects will be asked to take part in a 10 minute interview after the study is complete. If you will not be able to come for a follow-up visit, the interview may be done over the phone.

5. What will happen to you while you are in this research study?

If you are eligible for the study, you will be asked to complete a baseline questionnaire using the web-based collection platform, Research Electronic Data Capture (REDCap), about your emotional state after the transplant, what kind of social support you utilize and your quality of life. This questionnaire may take 20-30 minutes to complete. If you want someone to help you read the questions we will be glad to assist you. After the baseline survey, a Research Coordinator will provide more detailed instructions about the web-based video intervention via REDCap.

You will receive a reminder phone call and an email once every week (4 times) with a REDCap link that contains two intervention videos, instructions for you (patients and caregivers) to view and discuss the video together, and a short set of questions to evaluate immediate responses to the material. If you do not have access to the Internet, you can use the REDCap mobile app to complete the intervention on your own mobile device or on a tablet computer that we will loan to you for the duration of the study. After the 4-week intervention, you will be asked to complete questions similar to those at baseline, and additional questions regarding the video, and then again 3 months later to complete a smaller set of questions.

You will be connected to a biofeedback device (emWave Pro) with an ear or fingertip sensor for measuring your heart rhythm for a 3 minute baseline assessment (after completion of questionnaire), and then again for another 3 minutes immediately at post-intervention (4-weeks) after watching videos. You may be given the option of participating in a face-to-face interview in the clinic at one of your subsequent visits or over the phone by a Research Coordinator. The interview will be recorded.

6. What are the possible risks or discomforts from being in this research study?

The risks are minimal for this study. You might become upset if you are asked to answer questions about your transplant experience as a patient or a caregiver. If you become upset, you may stop participating at any time.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

8. What are the possible benefits from being in this research study?

This study is being done for research. Others may benefit in the future from what we learn in this research study.

You may benefit personally from this study because while watching stories about similar experiences, you may find some ways to cope with your emotional distress in a way that is similar to what the storyteller has adopted as strategies to cope.

9. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

10. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. The tests and procedures are:

- o Questionnaire completion
- o Viewing of videos
- o Discussion of videos with your patient or caregiver
- o Interview with study staff

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Research Billing at the telephone number provided in the Contact Information section of this form.

11. Will you be paid for taking part in this research study?

You will receive a $20 at baseline, a $25 after the 4 week intervention, and a $40 at month 3, for participating in this study. If you are able to complete the entire study, you will receive up to $85.

12. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Only the research study team will have access to the data. Data files containing your identifiable information will be kept in locked cabinets at the Mayo Clinic or Arizona State University. All electronic data files will be password protected. Your data will be kept for a minimum of 5 years after completion of the project. Paper data will be shredded; electronic data will be deleted. Consent forms will be kept in a locked file cabinet in a locked data closet accessible only to the Principal Investigator and designated research personnel.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- Arizona State University research staff involved in this study.

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With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts five years following the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature