ACT to Reduce Morbidity and Mortality in Hematopoietic Stem Cell Transplant (HCT) Patients

DUKE CANCER INSTITUTE

A National Cancer Institute-designated Comprehensive Cancer Center

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Consent to Participate in a Research Study
ADULT
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CONCISE SUMMARY

This is a research study to develop and test a novel protocol to reduce physical and psychological vulnerabilities that contribute to treatment intolerance and treatment-related morbidity and mortality among hematopoietic stem cell transplant (HCT) patients. When you enroll in this study, you will be asked to participate in acceptance and commitment therapy (ACT) as well as complete in-person physical function tests and a cognitive test. You will also receive training on how to use iOS devices (e.g. iPad, iPhone) and activity trackers (e.g. Apple Watch), which will be provided to you during the duration of your study participation. We will ask you to complete multiple surveys about your emotional and cognitive function, diet and social support, and ask you to provide feedback about the treatment (e.g., what you liked or did not like). We will also ask you to provide stool samples for analysis of the bacteria in your intestines, skin surface swabs for analysis of the bacteria on your skin and blood samples for analysis of biomarkers and metabolites. Biomarkers and metabolites are molecular and cellular parts that deal with your genetic makeup, like DNA, RNA, protein, and/or other naturally occurring substances that may be associated with transplant outcomes. You can expect to be enrolled in this study for 3 years.

This is a low risk intervention study that does not involve the use of an investigational drug or device. The main risk to this study is the risks associated with experimental psychological intervention. The other main risk associated with participating in any research study is a potential loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

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

You are being asked to take part in this research study of stem cell transplantation at Duke University Health Systems because you will be receiving an allogeneic hematopoietic (from a donor) stem cell transplant to treat your disease in the near future. Research studies are voluntary and include only people who choose to take part. 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. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

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WHO WILL BE MY DOCTOR ON THIS STUDY?

The study is being conducted by Dr. Anthony Sung and his study team. Dr. Sung will be your doctor for the study and will be in contact with your regular transplant and health care providers throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to develop and test a novel protocol to reduce physical and psychological vulnerabilities that contribute to treatment intolerance and treatment-related morbidity and mortality among HCT patients. The protocol is based on Acceptance and Commitment Therapy (or ACT). Our aims are:

- Optimize a brief ACT protocol (ACTivate) for HCT patients
- Evaluate the preliminary efficacy of ACTivate in improving physical function and other outcomes in HCT patients

We will also collect skin swab, stool and blood samples over the course of the study to evaluate microbiota diversity and biomarkers of inflammation and frailty.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 20 patients and up to 20 caregivers will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

The following surveys and assessments will be performed at baseline, day 30 (30 days after transplant), day 90 (90 days after transplant), day 180, year 1, year 2, and year 3. These study visits will coincide with regularly scheduled clinic visits (i.e. should not require a separate trip) and will be scheduled so as not to interfere with your clinic visits. The questionnaires you complete may be available to complete online, via RedCap, an online survey tool supported by Duke, at http://redcap.dtmi.duke.edu/redcap/. These surveys should take approximately 90 minutes to complete and may be split into two sessions if you prefer.

- Tests of physical activity and function
- Surveys to assess your physical function
- Surveys and evaluations to assess your cognitive function
- Surveys to assess your mental health
- Surveys to assess your nutrition and diet
- Surveys on your social support
- Questionnaires on your symptoms
- Assessments of your overall (global) function

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- Financial assessments
- Quality of life surveys
- A questionnaire about what it was like to participate in the treatment (day 90 only)
- You will also be asked to complete two brief surveys every 2-3 weeks about your psychological functioning. These surveys will be completed online using a computer or mobile phone. These surveys will take approximately 2-3 minutes to complete.

You will be asked to participate in 1-6 ACT sessions that will take place based on when works best for the patient and caregivers. The ACT sessions will be tailored to the clinical challenges of HCT. Sessions are with a mental health professional and are 45-60 minutes in duration and include both you and your caregiver. ACT sessions may be recorded for training purposes and only approved key personnel will have access to the audio recordings. Only Duke encrypted devices or Duke approved software will be used to record ACT sessions and audio files will be saved to secure folder behind the Duke server.

You will also be asked to provide the following biological samples:
- Skin swabs: 7 times- baseline (prior to transplant) day 30, day 90, day 180, year 1, year 2, year 3
- Stool sample (50 grams, size of a plum): 11 times- baseline, day 0, 7, 14, 21, 30, 60, 90, 180, year 1, year 2, year 3
- Blood sample (16 ml, approximately 3 teaspoons): baseline, day 14, day 30, day 90, day 180, year 1, year 2, year 3

When you consent to participate in ACTivate, you will receive training on how to use iOS devices (e.g. iPad, iPhone) and activity trackers (e.g. Apple Watch), which will be provided for your use during the duration of study participation. Your study iPad or iPhone may be pre-loaded with apps and/or PDFs including Technology Recordings to better Understand BMT (TRU-BMT) or SplendoFit, which you will enter in daily. The activity tracker and/or iOS device will be given to you at your assessment visit and collected on or before your year 1 visit. In rare circumstances, and with the study doctor's permission, we may allow you to use your personal device (such as a Fitbit). If you are allowed to use your personal activity tracker, we will only export activity data from your devices (such as a csv file) and will not be downloading the TRU-BMT or SplendoFit apps on your personal device.

HOW LONG WILL I BE IN THIS STUDY?
You can expect to be enrolled in this study for 3 years, depending on when your transplant occurs. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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WHAT ARE THE RISKS OF THE STUDY?
This is a low risk intervention study that does not involve the use of a study drug or device. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is also risk associated with experimental psychological intervention (ACTivate). Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Risks of Drawing Blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks specific to mobile apps:
Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on the device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of the device. Mobile apps may have unanticipated impact on the operations of the device (e.g., battery drainage). If you are loaned a Duke device for use during this study and you use it for nonstudy related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. When you return the device at the end of the study, the device will be cleaned to remove any of your personal information.

If the device is lost or stolen during the course of the study, please contact the study team immediately. The study team can then erase the device study data remotely if necessary and provide you with a replacement device. In the meantime, you are responsible for the general security of the device and the information on it.

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We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.
As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Other risks:
Stool Collection:
There are no known risks associated with the collection of stool samples. There may be risks, discomforts, or side effects that are not yet known.

Skin Swabs:
There may be irritation or injury to the skin when the swab is rubbed over the tissue. There may be risks, discomforts, or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. It is possible that the study interventions may improve your physical and psychological well-being and may improve your overall health during and after transplant. We hope that in the future the information learned from this study will benefit other people with your condition.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Older American Independence Centers (OAICs), Food and Drug Administration, the Duke University Health System Institutional Review Board, Duke University Office of Audit, Risk and Compliance - Human Subjects Research Compliance office, and representatives of the Duke Cancer Institute. If any of these groups review your research record, they may also need to review your entire medical record.

As part of the study, you will be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies

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done solely for this research study and not as part of your regular care will not be included in your medical record.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

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WHAT ARE THE COSTS?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Sung. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The study will cover the cost for services and procedures that are done solely for research purposes. Please talk with the Dr. Sung about the specific services and procedures that the study will pay for, and the ones for which you or your insurance will be responsible. We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?
You will not be compensated for your participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Sung at 919-668-5710 during regular business hours and at 919-668-1091 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.
Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Sung in writing and let him know that you are

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withdrawing from the study. His mailing address is DUMC Box 3961, 2400 Pratt Street, Durham, NC 27710.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. If this occurs, you will be notified and your study doctor will discuss other options with you. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ct2/home, 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, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Sung at 919-668-5710 during regular business hours and at 919-668-1091 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____		
Name of Person Obtaining Consent		