

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: *Sustaining Quality of Life of the Aged: Heart Transplant or Mechanical Support? (SUSTAIN-IT)*

Investigator: Kathleen L. Grady, PhD, RN, FAAN

Supported By: This research is supported by The National Institute on Aging (NIA).

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you, or someone you care for, has advanced heart failure meeting one of the criteria below and because Northwestern physicians participate in the Interagency Registry of Mechanical Assisted Circulatory Support (Intermacs) registry. Select one of the following:

- You are scheduled to receive a mechanical circulatory support (MCS) device for long-term treatment (known as destination therapy)
- You are listed with the United Network for Organ Sharing (UNOS) for a heart transplant (HT)
- You are a *caregiver* for a patient who is receiving a mechanical circulatory support (MCS) device for long-term treatment (known as destination therapy)
- You are a *caregiver* for a patient who is listed with the United Network for Organ Sharing (UNOS) for a heart transplant (HT)

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to compare the impact of heart transplant (HT) and mechanical circulatory support (MCS) devices on advanced heart failure patients and their caregivers who receive these treatments. For this study, researchers will be comparing health-related quality of life (HRQOL), symptoms, thinking, and adverse events in older (60-80 years) patients who undergo HT or receive MCS. They will also be evaluating HRQOL on the caregivers of this patient population.

We hope information received from patients and their caregivers about HT and MCS devices will provide physicians with a better understanding of how MCS and HT improves or does not improve HRQOL for heart failure patients and/or their caregivers. This information in turn may help guide physicians' decision-making processes when

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

determining which candidates are better suited for HT vs. MCS and help patients and their caregivers to better understand HRQOL after HT and MCS, so that they can make a more informed decision when they are offered one of these surgeries.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 24 month (2 years) or longer if you are a patient on the heart transplant list, as you may be on the list for a while.

You will be asked to complete questionnaires (patients and caregivers), undergo a brief interview (patients only), and complete walking tests (patients only) at 6-8 visits.

More detailed information about the study procedures can be found under the section **What happens if I say “Yes, I want to be in this research”?**

Is there any way being in this study could be bad for me?

Being in this study may make you feel uncomfortable when you answer some of the questions within the questionnaires or during the interview. Patients undergoing walking tests may experience shortness of breath, dizziness, fatigue, and falling.

More detailed information about the risks of this study can be found under **“Is there any way being in this study could be bad for me? (Detailed Risks)”**

Will being in this study help me any way?

While we cannot promise any benefits to you or others from your taking part in this study, all patients and caregivers will have a chance to share their thoughts, feelings, etc., via questionnaires. Additionally, knowledge gained from this study may help others with advanced heart failure or may help doctors better understand how MCS and HT improve or do not improve HRQOL for heart failure patients who undergo these procedures and/or their caregivers.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Who can I talk to?

If you have any questions about the study, you should call us promptly. Kathleen L. Grady, PhD, RN is the person in charge of this research study. You can call her at telephone # (312) 695-4860 or the study coordinator at (312) 926-4000 with questions about this research study Monday through Friday, from 9am to 5pm.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

Up to 400 patients and 400 caregivers will be recruited from 13 medical centers. We hope to enroll up to 50 patients and 50 caregivers here at Northwestern.

What happens if I say “Yes, I want to be in this research”?

As a participant in this study, patients and caregivers will be asked to undergo a brief interview (patient only) and complete several self-report instruments (questionnaires) before surgery (baseline) and at 3, 6, 12, 18 and 24 months after MCS or HT. Patients, and their caregivers, waiting for a heart transplant longer than 6 months will be asked to complete the interview and self-report instruments every 6 months and to also complete 2 of the instruments just before surgery. Completion of the interview will take about 10 minutes and completion of the instruments will take approximately 15-20 minutes each time and can be done during a follow-up clinic visit (preferred) or at home. Caregivers will also be asked to complete a brief health history questionnaire (medical and surgical history) at baseline and month 24/end of study.

If you are not able to complete the instruments on-site, you may complete them at home; in these cases a stamped, addressed envelope will be provided for you to return the instruments to the site. Your study coordinator will discuss your options for completing the follow up questionnaires with you.

Research personnel will review each instrument upon completion and will contact you if any items are left blank, if any responses are unclear, or if the questionnaires are not returned.

In addition, patients will also be asked to perform six minute walk tests (6MWT) and 5-meter gait speed tests at baseline and at 3, 6, 12, 18 and 24 months after surgery. The 6MWT requires you to walk a pre-measured distance for 6 minutes to determine how far you can go without stopping. The 5-meter gait test measures how long it takes to walk 5 meters. We will ask you to perform the 5-meter gait speed test three times at each time period. You will not need to complete these tests if you meet any of the following conditions: presence of palpitations or low blood pressure associated with changing position, unable to walk due to arthritis or any other bone or joint disease that limits your ability to walk, neuromuscular disease, chronic pulmonary condition or presence of chest discomfort with effort.

In addition, research personnel will review and collect information from patients' medical records throughout the study. If you received an MCS device, we will also collect information from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database. Per institution practice, patients receiving an FDA approved MCS device have their medical and health information entered into the INTERMACS database for quality assurance purposes. For this study, you agree to allow your medical and health information that is entered into the INTERMACS database to be shared with the study investigator, for as long as you have the MCS device implanted and for as long as you participate in this study.

The type of information that will be shared by INTERMACS with study investigators is: your medical and surgical history, medications you have taken or may be currently taking, information about your health and well-being, your physical activity level, complications after surgery, hospitalizations, vital signs (heart rate and blood pressure measurements), blood tests,

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

questionnaires you have completed about your feelings about your health (HRQOL), and the 6MWT. Importantly, if some of the instruments and walking tests that we will ask you to do are the same as those done for INTERMACS, we will not ask you to do the tests again, but rather we will collect the information from INTERMACS, who have joined us in this research.

If you have consented to participate in another heart failure study that collects some of the instruments and walking tests that we ask you to do, we will not ask you to do the test again. Instead, we will collect the information from the heart failure study.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you. If you stop being in the research, data that has already been collected will not be removed from the study database. You will be asked whether the investigator can continue to collect data from your routine medical care.

Detailed Risks: Is there any way being in this study could be bad for me?

Being in this study may make you feel uncomfortable when you answer some of the questions on the questionnaires or during the interview. If this occurs, you may choose not to answer some or all of our questions at any time. We can also refer you for counseling if you would like to do so.

Walking tests (patients only): During the 6MWT and 5-meter gait speed tests you can use your usual walking aids during the tests (cane, walker, etc.). Risks of these tests include shortness of breath, dizziness, fatigue, and falling. If at any time you experience any of these symptoms, the test will be stopped. You will be under the supervision of trained staff during these tests.

Will it cost me anything to participate in this research study?

There will be no costs to you for being in this study. Usual medical care costs including any tests, procedures and/or medications that are considered medically necessary for your disease or condition will be your responsibility or that of your insurance company. Anything that is done outside of the normal standard of care (i.e., self-report instrument, phone call follow-up, etc.) will be covered by the study.

Will being in this study help me in any way?

While we cannot promise you will personally benefit from participating in our study, all patients and caregivers will have the chance to share their thoughts, feelings, etc. via self-report instruments. Additionally, knowledge gained from this study may help others with advanced heart failure or may help doctors better understand how MCS and HT improve or do not improve HRQOL for heart failure patients who undergo these procedures and/or their caregivers.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

researchers will use the Certificate to resist any demands for information that would identify you. 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity and the US Office for the Protection of Human Research Protections, may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

A description of this study 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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes 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. Your health information we may collect and use for this research includes:

- All information in your medical record
- Results of physical examinations
- Medical and surgical history
- Information from HRQOL study questionnaires, interviews and walking tests
- Information on your MCS or HT surgery and follow-up care
- Questionnaires, walk tests, and other medical records information that are entered in the INTERMACS database (FDA approved MCS device patients only)

The following groups of people may give the researchers information about you: All current and previous health care providers, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital.

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is necessary for review by such parties or is required by law.

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research,

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study).

- Clinical affiliates, including but not limited the Rehabilitation Institute of Chicago (RIC), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this comparative effectiveness research may be tracked in an electronic database and may be seen by investigators running other studies that you are enrolled in and by your healthcare providers.
- Other University research centers and University contractors who are working on the study, including research staff in the Bluhm Cardiovascular Institute Clinical Trials Unit (676 N. Saint Clair, Suite 1700; Chicago); University staff responsible for overseeing study conduct, data collection and database maintenance.

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 persons may be able to share your information with others without your separate permission.

However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the receivers of the information except in precise situations allowed by law.

Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent or the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Your study results will be kept in a secure central data repository at Northwestern University, Chicago, IL 60611. This information may be used in the future by the study investigators to further study HRQOL in MCS and HT recipients. These results will be stored in the data repository by your name. However, access to any of your identifiable information (for example, your name, social security number, medical record number) will be limited to the study investigator and authorized research staff.

Results of this study may be used for teaching, research, publications or presentations at scientific meetings. In addition, we may share your information with other institutions that study heart disease so those researchers will have more information to study. Results shared with other researchers and institutions will never contain any personally identifying information. If your individual results are discussed, we will use a study code number, rather than your name or other identifying information, to protect your identity. Examples of identifying information include medical record number, social security number and address.

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. Any study information or other information from your medical record collected before your written notice of withdrawal may still be used for the study. Unless you "take back" (revoke) your consent, it will not expire. To revoke your authorization, write to:

Kathleen L. Grady, PhD, RN
Northwestern University, Division of Cardiac Surgery
201 East Huron St., Galter 11-140
Chicago, IL 60611

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 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.

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent