Consent and Authorization Form

Study Title: A multicenter trial of shared decision support intervention for patients and their caregivers offered destination therapy for end-stage heart failure: DECIDE-LVAD
Principal Investigator: Larry Allen, MD, MHS

COMIRB No: 14-2102
Version Date: 4/11/2016

You are being asked to be in this research study because you have advanced heart failure and are being evaluated for a left ventricular assist device for destination therapy, also called a DT LVAD, or you are a caregiver of someone with advanced heart failure and being evaluated for DT LVAD.

For patients who join the study, you will allow us to review your medical record over the next 12 months so we can better understand your disease progression and treatment choice. Both patients and caregiver who join the study will be asked to complete surveys about DT LVAD decision-making and your feelings and attitudes. These surveys will occur twice at baseline and once at 1-month and 6-months; you can decline to complete a survey at any time. If you are the caregiver, we may ask you to complete an interview so we may learn more about the process and your caregiving. You can refuse participation in any portion of this study and continue involvement in other parts of it. Your study participation will last about 6-months.

This study is designed to learn more about how patients and caregivers make decisions about their treatment choice and their satisfaction with the decision.

Possible discomforts or risks include feeling uncomfortable answering some questions. You can refuse to answer questions at any time. There may be risks the researchers have not thought of. There are no direct benefits to you.

Every effort will be made to protect your privacy and confidentiality by keeping identifiable information separate from study data and keeping all data in a secure location only accessible by study personnel, including a secure and password protected online database and in a locked file cabinet.

This research is being paid for by the Patient Centered Outcomes Research Institute.

You have a choice about being in this study. You do not have to be in this study if you do not want to be. Participation is always voluntary and you can refuse participation in any portion or all of the study at any time without penalty.

If you have questions, you can call Dr. Larry Allen at 303-724-4713. You can call and ask questions at any time.

You may have questions about your rights as someone in this study. If you have questions, you can call the COMIRB (the responsible Institutional Review Board). Their number is (303) 724-1055.

 Initials_____

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Larry A. Allen, MD, MHS
University of Colorado Denver
12631 E. 17th Ave, Mail Stop B130, P.O. Box 6511
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Patient Centered Outcomes Research Institute, who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Billing or financial information

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator: _____ Date: _____
Investigator must sign within 30 days

Witness: _____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐