CONSENT FORM FOR RESEARCH

*This form is for use in a research study that may involve subjects that do not have the ability to consent to take part in the study. When the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject. It does not refer to the person (legally authorized representative) who is signing this form for the subject.

Study title: Randomized Trial to Compare the SherpaPak™ Device vs Cold Storage of Donor Hearts in Transplantation: A Pilot Study

Study support provided by: Cedars Sinai Research Institute

Cedars-Sinai Principal Investigator: Fardad Esmailian, MD

Study contact phone number at Cedars-Sinai: 310-248-7132

After-hours emergency contact (24 hours): 310-248-8300

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part or stop taking part.

- **Purpose:** The purpose of this study is to see which method of organ preservation leads to better outcomes for donated hearts.

- **Procedures:** The main things that will happen in this study is that the heart transplant team will transport the donor heart using either the SherpaPak™ device or cold storage, whichever method to which you are randomized. Both methods of transportation are FDA approved.

- **Duration:** Taking part in this study will last about 30 days (+/- 14 days in the event your week 4 biopsy gets delayed).

- **Risks:** All research studies involve some risk. Risks or discomforts from this study may be damage to the donor heart.

- **Benefits:** You are not likely to be helped from taking part in this research study. But the information learned from this study may help others in the future.

- **Alternatives:** You can choose not to take part. Please talk about these choices with the study team.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to see which method of organ preservation leads to better outcomes for donated hearts.

There are two methods of organ preservation. The first method is the use of cold storage. With this method, the donor heart is stored in preservation fluid within bags that are then placed on ice and transported in a cooler. This is the usual method for transporting donor hearts. This is also known as "standard of care."

The second method is the use of the SherpaPak™ Cardiac Transport System. With this method, the donor heart is kept at a steady, consistent temperature throughout transportation. This method is not typically used for transporting donor hearts.

The U.S. Food and Drug Administration (FDA) has approved the SherpaPak™ Cardiac Transport System as it is being used in this study.

You are being asked to take part in this research study because you are in need of a heart transplant. If you decide to take part in the study, your donor heart will either be placed in cold storage or the SherpaPak™ Cardiac Transport System.

The study will include up to 20 people in total.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the flowchart of procedures. The flowchart is given with this consent form.

The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related and which are standard of care (routine). **Research-related procedures** are procedures done only for the research study. They would not be performed for your routine

care outside of the study. **Standard of care (routine) procedures** would be performed as part of your routine care even if you did not take part in this study.

Section 5 in this form describes the common medical procedures that will be done or repeated only for this research study.

Description of main research procedures:

On the day of your transplant operation, your doctor will ask if you still want to take part in the study. If you decide not to take part in this study, your heart transplant and follow-up care will not be modified in any way. If you decide to take part in the study, you may change your mind at any time up to the moment you are sedated or under anesthesia.

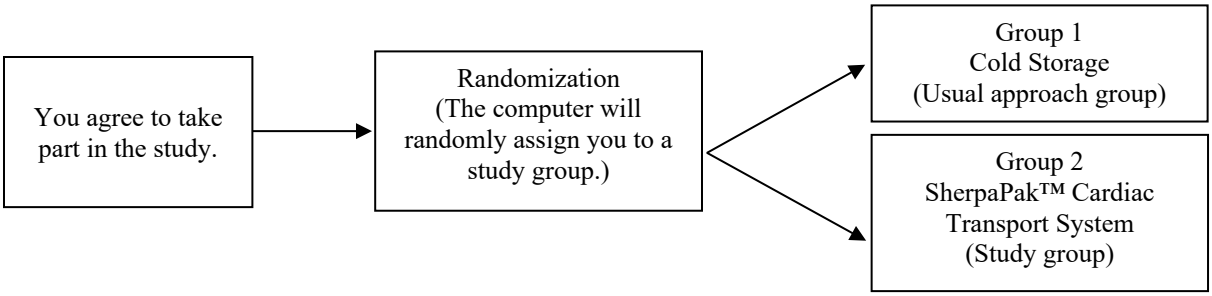
Your doctor will decide if the donor heart is suitable for transplant and an appropriate match for you. It is possible that the donor heart found for you may not be suitable for you. If the heart is suitable for you, the heart transplant team will transport the donor heart using either the SherpaPak™ device or cold storage, whichever method to which you are randomized. After your heart transplant, you will visit the clinic per your physician's instructions.

This study has 2 study groups:
You will be randomly assigned to a group in a 1:1 ratio.
- 50% chance of receiving your donor heart using the SherpaPak™ method, or
- 50% chance of receiving your donor heart using the cold storage method.

This is done because no one knows if the results experienced by the participants in one study group are better, the same, or worse than the results experienced by participants in the other. Once you are put in one group, you cannot switch to another group. If you are randomized to the SherpaPak™ group and the SherpaPak™ transport system is not available, your transplant will **not** be delayed. We may instead switch you to the cold storage group or remove you from the study.

This is a randomized research study.
- **Randomized**: This means that you will be put in a study group by chance (like flipping a coin). You will be randomly put in one of the above study groups. You will have a 1:1 chance of being placed in any one of the groups described above. A computer will randomly put you in a study group. We do this because no one knows if the results in one study group are different than the others. The results could be better, the same or worse than the results in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.

The chart below outlines what will happen during the study.



The research team will analyze data from your medical records from your heart transplant and clinic visits up to 30 days after your heart transplant.

Biopsy tissue from your new heart will be tested to look for changes in mitochondrial function and quality. Tissue will be taken immediately after the heart is obtained, just prior to transplant, and during your routine biopsy visit one week after your transplant.

The samples taken from your donor heart will be collected solely for research purposes. These samples would otherwise not be taken if you did not participate in this research study.

There will be no additional tests, visits, surgical or medical procedures beyond what would routinely happen during and after your heart transplant procedure.

How long will you be in the study?
We think you will be in this study for/until about 30 days (+/-14 days in the event your week 4 biopsy gets delayed).

4. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

Risks of common medical procedures performed for research purposes are described below in Section 5. Side effects and risks of standard of care procedures are not described in this consent form.

Cold Storage
With the cold storage method, it is difficult to control the temperature of the organ. This could damage the donor heart if the temperature is too cold. Before you receive the heart transplant, the surgeon will examine the organ to make sure it is suitable for transplantation.

SherpaPak™ Cardiac Transport System
With the SherpaPak™ method, although the temperature of the donor heart can be controlled, it is possible that the device could malfunction during transport and the temperature will no longer be controlled. Before you receive the heart transplant, the surgeon will examine the organ to make sure it is suitable for transplantation.

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long. However, in some cases, they can be serious, long-lasting, permanent and/or fatal.

5. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Medications: We will ask you about your past and current medications. Talk with the study team about any non-study medications. Non-study medications include over-the-counter drugs, supplements and vitamins.	This does not have any physical risks.
Remnant Samples: We will collect left-over samples from your standard-of-care biopsies to conduct research-related tests.	There does not have any physical risks.

6. Benefits From Taking Part in the Study

You should not expect to benefit from taking part in this research study.

We hope the information learned from this research study will benefit other individuals waiting for heart transplantation in the future by helping us to learn whether the SherpaPak™ Cardiac Transport System or cold storage is better for heart transplantation.

7. Whether Research Results Will Be Shared

Some of the research tests done in this study follow standard clinical procedures. These are performed in certified clinical labs. These test results may be shared with you. They may be placed in your Cedars-Sinai medical record.

Other research tests done in this study are for research purposes only. They are performed in a research only lab where the results are not for clinical use. These research-only results will not be shared with you. They will not be put in your Cedars-Sinai medical record.

Unanticipated Incidental Findings
We will contact you using the last contact information you gave if, unexpectedly, we find results that suggest potentially clinically relevant medical information. We may suggest you talk with your treating physician about possible additional clinical testing to further evaluate the research finding. You and/or your insurance would pay for any additional testing and any related treatment.

8. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

9. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

10. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitor the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

We might share your information and/or research samples collected in this study. It might be shared with other researchers at Cedars-Sinai, other academic institutions or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

11. Research-Related Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

12. Financial Considerations

Costs of Participation
The attached flowchart lists items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the Study Sponsor. Review the flowchart for details.

Standard of care procedures and the cost of the transplant procedure, and related items, drugs and procedures, will be charged to you or your insurance company. You remain responsible for all deductibles, copays and balances under your health benefit plan.

The research staff will seek pre-authorization from your insurance company for the related procedures. Before any study procedures are performed, pre-authorization must be received from your insurance company. If your insurance company denies coverage, you may decline to take part in this study or you may choose to pay out of pocket. If you have questions or concerns about your insurance coverage, you should ask your health benefit plan.

Payment
You will not be paid for taking part in this research study.

You will not be paid for giving biological samples (e.g., blood, fluid, tissue) for this study. Once you give the samples for the research, you no longer have access to them. Cedars-Sinai or the Study Sponsor will own your donated samples. Researchers might use your samples to develop new products, tests or discoveries. These inventions may result in commercial profit for the researchers, Cedars-Sinai and other organizations. If this happens, you will not receive any financial benefits.

Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

13. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Randomized Trial to Compare the SherpaPak™ Device vs Cold Storage of Donor Hearts in Transplantation: A Pilot Study" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☒ Pathology reports
☐ Imaging reports (e.g., x-rays or scans)
☐ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Mental health records
☐ Billing records

☒ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation

☐ Other tests or other types of medical information: none

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.

- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Flowchart of Visits, Tests and Procedures

Procedures/Assessments	Screening Visit	Visit 1 (Day 0 at Transplant)	Visit #2 (Day 7 post-transplant ± 2 days)	Visit #3 (Day 14 post-transplant ± 2 days)	Visit #4 (Day 21 post-transplant ± 2 days)	Visit #5 (at hospital discharge)	Visit #6 (Day 30 post-transplant ± 14 days)
Eligibility & Informed Consent	R						
Demographics/Characteristics	S						
Medical & Cardiac History	S						
Confirm Eligibility/Randomize		R					
Patient visit (physical exam)	S	S	S	S	S	S	S
Tissue Collection for biopsy (donor heart prior to transport & prior to transplant)[1]		R[1]	R				
Mitochondrial Testing		R[1]	R				
SherpaPak Cardiac Transport System[2]		R					
Cold Storage Transport[3]		S					
Endomyocardial Biopsy (recipient)			S	S	S		S
Data Collection							
Transplant Details		R					
Donor Characteristics		R					
Right Heart Catheter Data		R					
Use of Invasive Ventilator Support		R	R				
Primary Graft Dysfunction (PGD) Scores (scores related to signs of injury in the transplanted heart)		R	R				R
Medications Used (use of certain medication to increase the force of your heart beats, immunosuppressive medications, etc.)		R	R			R	R
Use of Mechanical Circulatory Support		R	R			R	R

Procedures/Assessments	Screening Visit	Visit 1 (Day 0 at Transplant)	Visit #2 (Day 7 post-transplant ± 2 days)	Visit #3 (Day 14 post-transplant ± 2 days)	Visit #4 (Day 21 post-transplant ± 2 days)	Visit #5 (at hospital discharge)	Visit #6 (Day 30 post-transplant ± 14 days)
Data Collection							
Post-Transplant Hemodynamics (how your blood is flowing)		R	R				R
ICU & Hospital Stay Information						R	
Heart transplant related adverse events		R	R	R	R	R	R
Patient Survival							R
Transplanted Heart Survival							R

LEGEND
R = Research item/procedure done only for research purposes and covered by the study
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance

Footnotes:

1 – to be done twice (prior to transport and prior to transplant)

2 – only if recipient heart is randomized to be transported with the SherpaPak System

3 – only if recipient heart is randomized to be transported using cold storage

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the participant or legal representative
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Name of Participant (Print)	Signature of Participant	Date of Signature

If participant is unable to sign the form, please state the reason below:

Signature of Legal Representative	Relationship to the Participant	Date of Signature

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Name of Participant (Print)	Signature of Participant	Date of Signature

(if applicable)

Signature of Legal Representative	Relationship to the Participant	Date of Signature

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness
(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subject who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred, and that the individual verbally consented to participate in the research.)

Interpreter/Witness name (please print)	Signature	Date

To be marked at time of signature:
Consent obtained:
☐ *From non-English speaking individual with assistance of interpreter*
☐ *From English speaking individual who is not physically able to sign the consent document*