Version date 06/25/25

Deceased Donor Kidney Storage at 10 Celsius versus Conventional Storage

Informed Consent Form

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VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: Deceased donor kidney storage at 10°C versus conventional storage
Version Date: 06/25/25
PI: W. Christian Crannell MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

This study will test how storage of donor kidneys affects kidney function after transplant. Historically, deceased donor organs (heart, liver, lung, kidney) have been stored at 4°C. However, new science suggests that 4°C may be too cold and actually contributes to kidney damage. Animal and human clinical data from lung transplant show good clinical outcomes with 10°C storage of donor organs. Heart transplant has also moved away from 4°C to avoid potential organ injury. Preliminary animal data also shows that 10°C storage results in healthier donor livers. Dr. Crannell's team (leading this study) has data that kidneys stored at 10°C make more urine and have better blood flow.

In our study, some kidneys will be stored at 10°C (experiment), and some will be stored at 4°C (our usual standard of care), and we will compare kidney function between kidneys. If you participate, we will collect urine from your Foley catheter after your transplant. Your urine will be analyzed for a molecule (NGAL) that measures kidney injury. We will also collect medical information from your chart to help us understand your kidney function. These data will be stored with a study ID number so you cannot be identified. Nothing else about your transplant care will change. Declining to participate in this research will not impact your care or your ability to receive a transplant.

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

You are being asked to take part in this research study because you have been called in for a deceased donor kidney transplant.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Taking part in this study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and that have not been seen in humans to date. Please call the study doctor if you have any side effects, even if you do not think it has anything to do with this study.

Storing your kidney at 10°C has the possible risk that your post-transplant kidney function could be worse, and you may have an increased need for post-transplant dialysis.

The following list includes some other risks associated with kidney transplantation that are possible even if you don't participate in the study. It is unknown whether the frequency of these adverse events will be any different with 10°C organ storage:
- Bleeding
- Infection
- Problems related to the heart
- Failure of the transplanted kidney to function successfully
- Rejection of the transplanted kidney
- Side effects associated with immunosuppressive medications

Your medical record number will be retained in the research data file that will be stored on Vanderbilt University Medical Center servers on a HIPAA compliant database known as REDCap. This data file will be used to collect data from your electronic health record. There is the potential for a data breach that could identify your samples.

Good effects that might result from this study:

You may or may not receive direct benefit from being in this study. Your waitlist status and wait time won't be affected by your study participation. Information learned from this study may help kidney transplant patients and healthcare professionals in the future.

The results from this study may help the transplant community understand how to store donor organs to allow the best kidney function after transplant. This could result in a change in the standard of care regarding organ storage. There may be a significant increase in kidney transplants with immediate organ function, with no need for post operative dialysis.

Procedures to be followed:
Your kidney will be stored at either 10°C (experiment) or 4°C (standard care) after being removed from the donor. After your transplant, urine will be collected from your catheter and analyzed for a biomarker called NGAL which increases with kidney injury. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. Your medical record will be accessed and clinical information about your transplant will be recorded in HIPAA-compliant secure database known as REDCap.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.
You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury. There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

There are no plans for Vanderbilt or DCI to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or DCI give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the principal investigator on the study Dr. W. Christian Crannell at (615) 936-0404.

For additional information about giving consent or your rights as a person in this study, to discuss

problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

A portion of this study will include data collection where your medical chart is reviewed, and items related to your transplant will be recorded. This information is kept in a secured and encrypted database, with safeguards in place to limit release of information. Only Dr. Crannell and trained key study personal will have access to this database.All samples collected for this study will be deidentified and assigned a study identification number. This study ID will also be recorded in the database. The key to re-identifying this study ID will be locked in the study office in addition to the secured and encrypted database. The results of tests using your samples will not be recorded in your records, and no one outside of the study personal will be allowed to see these results. Samples collected as part of this research study will be kept indefinitely and may be used in the future to measure other biomarkers of organ function.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

The new products or tests may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact Dr. W. Christian Crannell at (615) 936-0404 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Study Results:

Study results will not be shared with you.

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use, or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form, and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer
	Printed Name of patient/volunteer

Consent obtained by:

Date	Signature
Time	Printed Name and Title