CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: Diabetes Endothelial Keratoplasty Study (DEKS): Impact of Diabetes on Corneal Transplant Success and Endothelial Cell Loss

STUDY DOCTOR'S INFORMATION

Name:
Contact Number:
Site Name:
Mailing Address:
Emergency (24-hour) Number:
Study Coordinator Name/Contact:

SUMMARY

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time.

- **The study is being done to see if a cornea donor's diabetes status affects corneal transplant success. Your surgeon has suggested a cornea transplant for you, called a Descemet Membrane Endothelial Keratoplasty, or DMEK, for one or both of your eyes. This is why you are being asked to be in the study.**

- **This is a data collection study. There are no experimental study procedures other than assigning the type of donor cornea that is placed. It is expected that the risk for the study is about the same as the risk you would have if you were not in the study.**

- **You will be asked to be in the study for about one year for each eye that is studied. The study will involve corneal transplant surgery. The surgery will be performed the same way whether or not you are in the study. However, the way the donor is chosen for you will be different. It will follow special procedures for the study. Neither you nor your corneal surgeon will know if the donated cornea was from a diabetic or non-diabetic donor. The study will collect data from your regular care visits. There will be a few extra tests during three of these standard visits including a finger prick to get a blood sample, and pictures of your cornea.**

- **The most likely risk is that you may have brief pain, bruising, and temporary discomfort from the finger prick to collect your blood. Also, it is possible that a transplant from a donor with diabetes may not be as successful as a transplant from a donor without diabetes, but this is what we are trying to find out. The other risks and discomforts of corneal transplant surgery will be the same as it would be if you are not in the study.**

- **It is not likely that you will have any benefit from being in this study. We hope that what is learned from this study could help people in the future.**

- **If you do not want to be in the study you can still get care and have a transplant like you normally would.**

WHAT IS INFORMED CONSENT?

You are being asked to take part in a research study. Taking part is voluntary. You can choose whether or not you want to be part of the study. You can take as much time as you need to think about whether or not you want to be in this study. You can also discuss the study with friends, family, or doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered. If you decide to be in the study, you will need to indicate at the end of this form that you want to be in the study. You will be given a signed copy of this form for your records.

If you have any questions before you decide to participate, you can talk to your study doctor, or you can call the Case Western Reserve University (CWRU) Study staff at 216-844-7984 or email visionresearch@uhhospitals.org.

WHO IS DOING THE STUDY?

This study is being led by researchers at Case Western Reserve University in Cleveland, Ohio and the Jaeb Center for Health Research in Tampa, Florida. It is being paid for by a grant from the National Eye Institute (NEI). The NEI is one of the National Institutes of Health of the U.S. Department of Health and Human Services, a part of the federal government. Other funds to support the study have been donated from multiple eye banks, individuals, and societies too.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to see if a donor's diabetes status affects the success of corneal transplants. The cornea is the clear window in the front of the eye. It is not known if diabetes in the donor affects the success of the transplant, but this is what we are trying to find out. This study will include about 1420 patients that have DMEK surgery. Patients will have surgery at about 30 sites throughout the United States. About 16 eye banks will process the donor corneas used in the study. You will be asked to have about three visits to the study doctor's office and be in the study for about a year.

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, you must:

- Be recommended for corneal transplant surgery by a surgeon
- Be able to understand what it means to be in the study and what you are being asked to do
- Be at least 30 and less than 91 years old
- Be able to schedule DMEK in at least one eye between 5 and 90 days from the date you sign this consent
- Be willing to return to the study site for follow-up at 1 month and 1 year
- Speak English or Spanish
- Be able to have blood collected through a finger prick
- Have at least one eye with certain conditions that are treatable by DMEK

Also, you cannot:

- Be pregnant or planning to become pregnant before surgery
- Have certain abnormalities or findings in your eye which disqualify the eye from the study
- Have your other eye (non-study eye) with very poor vision that is not correctable with DMEK

WHAT WILL HAPPEN IN THIS STUDY?

Your surgeon has determined that the back cell layer of your cornea (the endothelium) and the membrane it is attached to (Descemet membrane) are not working properly. Your surgeon plans to perform a procedure called Descemet membrane endothelial keratoplasty or DMEK. The DMEK takes off the unhealthy layers and adds a donated corneal endothelium and Descemet membrane from someone who has died (the donor). This new part of the cornea is called the donor cornea. About 1 in 10 people in the United States have diabetes and it is believed that 1 in 3 people who have donated a cornea had diabetes. That means, for every cornea transplant a person has, there is about a 1 in 3 chance of getting a cornea from a donor that had a known diagnosis of diabetes.

- For this study, if only one eye has a transplant, there will be the same chance (about 1 in 3) you will get a cornea from a donor who had diabetes. The donor cornea for the transplant you receive in the first eye will be determined by chance, like flipping a coin. This means that you and the study doctor will not get to pick which donor cornea you will get and you will not be told.
- Some people might have a transplant in both eyes as part of this study. If your second eye has a transplant and your first eye had a transplant from a donor with known diabetes, there will be a lower chance (much less than 1 in 3) you will get a cornea from a donor who had diabetes. The donor cornea for the transplant you receive in the second eye will be determined by the study team who will try to pick a cornea from a donor without known diabetes. If your first eye had a transplant from a donor without known diabetes, the second eye will still have about a 1 in 3 chance of getting a cornea from a donor that had diabetes. Overall, if you have a transplant in both eyes in this study your chance of getting a cornea from a donor with known diabetes in both eyes is less than it would be if you are not in the study.

The study will take about one year to complete for each eye that is studied. If both eyes are studied, then the DMEK procedures have to be at least 7 days and no more than 6 months apart. The DMEK procedure will be the same as it would be if you were not part of the study. The study has set standards for the donor cornea to make sure that the donor cornea you receive will be at least as good as the donor cornea you would get if you were not in the study.

You will be asked to have follow-up visits about one month, and one year after surgery for each eye that is studied. You may see your doctor's office more often as part of your regular care. At each visit, information will be gathered from the exams that your doctor's office normally does to take care of your eyes.

During your normal visits, you will also be asked to:

- have your finger pricked to check your hemoglobin A1c levels (HbA1c). This is a blood test for diabetes. The test indicates your blood sugar levels over the previous 3 months. It may indicate

whether you have diabetes or not. It will be done around the time of surgery and at about one year after surgery. You will be provided your HbA1c value after each test. We want you to share the result with your primary healthcare provider. If the HbA1c suggests that you may have diabetes that you did not know about, the study doctor's office will contact your primary healthcare provider or give you a referral to one. Or, if you already know you have diabetes, and the HbA1c value suggests your diabetes is not under good control, the study doctor's office will contact your primary healthcare provider or provide referral to one, if needed.

- have pictures taken of your cornea. The picture is used to see how well the transplant is doing. The pictures will be taken at about one month and one year after surgery.

A summary of the data we are collecting and the study timeline are outlined below:

Visit	Study Related Tasks		
	Collect standard of care information from your clinical record	Finger prick Blood Sample	Corneal Photographs
Baseline/Enrollment	X	X	
Surgery	X		
Visits between surgery to 1 Month Visit (as scheduled by your doctor)	X	X[1]	
1 Month Visit	X	X[1]	X
Visits between 1 Month and 1 Year (as scheduled by your doctor)	X		
1 Year Visit	X	X	X

[1] Only if not already completed

WHAT ARE THE RISKS OF THIS STUDY?

It is not expected that there would be any significant risks from being in this study. Anytime you have your finger pricked you may have bruising, discomfort, bleeding, or infection. These risks are possible but unlikely, and usually mild. This study will involve asking you some questions about your health history. If any questions make you uncomfortable, you can refuse to answer. You could find out that you may have diabetes that you did not know about, or, if you already have diabetes you could find out that your diabetes is not under good control. This might make you uncomfortable. However, this will also alert you to get helpful medical advice that you may need. You can decide to take a break or stop taking part in the study at any time. There is no risk for the corneal photographs.

Unknown Risks

It is always possible that anyone having a transplant could have a negative effect or reaction. Also, there may be additional risks from the study procedures that are not known. If we find out that there are any

new risks, you will be told about them. You will be able to decide if you want to continue in the study based on this new information.

Risks to Confidentiality

This study will be capturing some information about you that includes identifiable, personal information, like your date of birth. The study has procedures in place to protect that information. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the "How will my information be protected and kept confidential" section below for more information.

Risks of DMEK Surgery

Since the DMEK will be the same if you are in the study or not, this form does not list all the possible risks of DMEK surgery. You will talk about the risks of the surgery with your surgeon and you will be asked to sign a separate consent form for that procedure like you normally would. However, the most common risks of DMEK surgery and risks that may be associated with the diabetic status of the donor cornea are listed below:

- About 5% of the time or less, your body's immune system produces an inflammation of the donor cornea. This is often called a "rejection" reaction. The rejection reaction is usually reversible if treated promptly with cortisone eye drops. However, it sometimes leads to failure of the transplant and swelling of your cornea that may require another corneal transplant.
- Rarely, a serious infection develops inside the eye (endophthalmitis). This needs prompt treatment. It may cause permanent loss of vision or in severe circumstances loss of the eye.
- Rarely, an infection of the cornea develops that requires immediate treatment. It may result in permanent scarring and possible permanent loss of vision requiring a repeat of your corneal transplant.
- The pressure in your eye may go up (glaucoma). This can occur very quickly or slowly over time.
- The donor cornea can move out of position or detach. If it cannot be reattached, another corneal transplant may be required to restore the vision.
- Corneal swelling can occur. This may or may not be reversible. If not reversible, another corneal transplant may be required to restore the vision.

Study Contacts

The study staff may use your contact information to call, text or email you during the study. They may do this to send you things like reminders. They are not allowed to send your identifiable health information by text or email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. However, your email, phone number and your name will likely be in the text or email. If you think that the study staff have texted or emailed information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or email the study staff it is unsecure and what you put in the text or email is not protected.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

People who take part in this research study will add to new knowledge that may help other people who need a corneal transplant.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

Since this is a data collection study you can get care like you normally would. Your surgery will still be done even if you are not in this study. You will not be treated differently as a person if you do not want to be in this study.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time. The study may stop at any time, or the study team can stop your participation at any time. You do not have to give permission for the study to stop, or for your participation to be stopped by the study team. You will be told if this happens. If you withdraw, are removed from the study, or the study is stopped, you may continue to receive care like you normally would if you were not in this study.

You can decide to stop being in the study and/or stop getting text message or email contacts at any time. You will need to tell the study staff if you would like to stop. You can still be in the study if you do not want to get text messages or emails anymore.

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want to continue in the study based on this new information.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The cost of your routine care will be covered like it normally would be if you were not in a study. The study related corneal pictures and finger stick will be paid for by the study. Any additional tests and procedures as part of your regular care will be billed to you or your insurance company like they normally would.

Please ask to speak to someone at your study doctor's office or hospital if you want more information about what you or your insurance will be expected to pay.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If you take part in the study, you will receive up to $50 for participation. These payments will be paid as follows in the form of a gift card:

- 1-month Visit: $25
- 1-year Visit: $25

If you withdraw from the study, you will still be paid for the visits that you have completed. You will not receive extra payments for visits that are required as part of your normal care or for visits that are for treating an illness or injury.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. The samples collected will not be used for whole genome sequencing or other genetic research.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

This is a study with about the same risk as there would be if you were not in the study. For this reason, it is not expected that there would be any study related illness or injury. If you have an illness or injury that is related to your participation in the study, then you can get care like you normally would. The study does not plan to provide costs for care or other expenses relating to illnesses or injuries.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have any questions, concerns or suggestions about this study, then please contact your study doctor using their contact information on page 1, or contact the CWRU study team at 216-844-7984 or email visionresearch@uhhospitals.org.

Also, you can contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Unless the law requires it, your name, email address, or any other direct identifying information will not be used to identify you.

Certificate of Confidentiality

The National Eye Institute has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies you and allows us, in some cases, to refuse to give out information that could identify you without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If you need medical help, we may still share your identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your identifiable information. Your study doctor and research team will follow local laws to tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of you; and
- if your study doctor or research team learn that you plan to harm yourself or someone else

Purpose of Authorization
We have rules to protect information about you. Federal and state laws also protect your information. By signing this form you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must sign this form, including the Protected Health Information Authorization statement in the signature box at the end of this form if you want to be in the study. When you sign the form, you give permission for the use and sharing of your Protected Health Information (PHI) for the study. PHI is health information that identifies you. Your authorization is beneficial and important for the study. Without your authorization, you will not be able to be in this study.

Using and Sharing Your PHI
Information will be collected about you in this study. This information includes your name, email address, date of birth, address, telephone number(s), secondary contacts and information from your medical records. These are examples of identifiable information. A copy of the information will be kept at the Jaeb Center for Health Research in a limited access database which will be available to a few researchers at Case Western Reserve University. This will allow the central study team to assist your study doctor's office in contacting you and scheduling follow-up visits if your study doctor's office is unable to reach or locate you. Also, new information may be linked to this other information and may include the PHI described. The researchers at Case Western Reserve University will be able to link your name and study information but they will keep that information confidential to the extent permitted by law.

You will be identified in the research records by a code name or number. The data and corneal photographs taken specifically for this study will be collected, reviewed and stored in a centralized computer in the Cornea Image Analysis Reading Center (CIARC) at Case Western Reserve University (Cleveland, OH) which will only have the code name or number and not any PHI except the date the pictures were taken. If your doctor took any other photos of your study eye as part of usual care, those photos may also be shared with the central study team, but no one will be able to identify you from these pictures, and other than the date the photos were taken, there will be no other PHI included.

Your name will be listed on study forms shared between the Jaeb Center for Health Research, the study eye bank processing the donor cornea, and your study doctor's office. Your study doctor's office may need to give more PHI to the eye bank. This may include information that links your name and other personal information with the donor information. This information needs to be collected because the eye bank must know who got the donor corneas for standard safety practices. That additional information will be maintained locally by the eye bank and is only used to track the donor cornea by the eye bank and will not be stored at the Jaeb Center for Health Research.

Your blood samples will be sent to the Advanced Research and Diagnostics Laboratory at the University of Minnesota in Minneapolis, MN. The samples will be sent with the code number only and will not identify you.

Study data, pictures and results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting.

The study doctor's office will not share study results that can identify you except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your study PHI.

Who Can Receive and Use Your Study Information?
It is possible that people outside the Jaeb Center may need to see or receive your information from this study. Some examples include government agencies (such as the National Institutes of Health), committees that monitor safety, other sites in the study, and companies that sponsor the study. In most cases the information will have a code number with it instead of your name or email address.

There are some situations where the information will not have a code number but may include your name, email address, or phone number. Everyone who needs to see your information will be told it is confidential, but we cannot guarantee full confidentiality.

The following people or companies involved in this study may see your study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- The hospital where your surgery will happen
- The eye bank providing the donor tissue
- Jaeb Center for Health Research
- Researchers and their collaborators at Case Western Reserve University
- The doctors and other researchers who are involved in the study
- Advanced Research and Diagnostics Laboratory, University of Minnesota
- National Eye Institute
- Data Safety Monitoring Board (DSMB)

Can You Cancel Your Authorization?
You may cancel your permission for the use and sharing of your study PHI at any time. You will need to contact the JCHR IRB to cancel this. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about you will be gathered for the study, except when there is a safety concern related to the study. If there is a safety concern, your entire medical record may need to be reviewed. The Jaeb Center and Case Western Reserve University will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study. Any information that has been received will remain in the study database after you withdraw.

When Will the Use and Sharing of Your PHI Stop?
Some of your study PHI does not have a code number with it. Your permission for the use and sharing of your PHI lasts 50 years from the date that you sign this form or until the end of the study, whichever comes first. The rest of your study information does have a code number with it. When it is collected, it

becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your name or email address.

Other Considerations

The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any information that could identify you. There may still be a chance that someone could identify you, but this is not likely. The study results will also be made public. These results will not have any information that could identify you.

A limited dataset that contains some PHI may be provided to certain researchers. This PHI will not include things like your name, address, identifying pictures, or medical record numbers. Any researcher would need to sign an agreement to protect your PHI before getting this dataset as required by law.

Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting.

The final published findings and type of cornea you received will be provided to your study doctor to share with you at the end of the study. Some of your information from this study may be stored separately from or added to your medical record. You will not be able to see most of this information if you want to. If your regular doctors require it for your care, they will be able to view it. You have the right to see or copy your study records however the type of cornea you got will not be listed in these records.

Clinical Trial Reporting

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by 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. A copy of one of the study consent form templates will also have to be posted on a federal Web site.

AUTHORIZATION AND AGREEMENT TO BE PART OF THE STUDY

Adult Study Participation

By signing below, you agree to take part in this study. Your signature means that:

- you have read this informed consent form
- you have been given the chance to discuss the study and to ask questions to your satisfaction
- you freely choose to participate and you can withdraw at any time
- you will receive a copy of this consent form
- you authorize the use and disclosure of your protected health information. This information is collected as part of participation in this study. You/the participant cannot be in this study if you do not provide this permission.

_____ _____

Participant's Signature Date

Permission to Contact for Future Related Studies

Would you be interested and willing to be contacted in the future about other studies related to this study that you might be eligible for**?**

☐ **YES**, I do give my permission to be contacted in the future about other studies related to this study that I might be eligible for

☐ **NO,** I do NOT give my permission to be contacted in the future about other studies related to this study that I might be eligible for

Designated Person Obtaining Consent

I certify that to the best of my knowledge the participant is who they say they are, has the capacity to consent, and understands the nature, demands, risks, and benefits involved in the participation of this study.

_____ _____ _____

Investigator or Designee's Printed Name **Investigator or Designee's Signature** **Date**