

**DONOR MANUAL**  
**Keratolimbal Allograft**  
**TRANSPLANTATION**

**TORONTO**

**Limbal Allograft Transplant**

**PROGRAM**



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## ***Introduction***

This manual is written for people who want to learn about living stem cell donation. It includes information on the rationale for living donation, the assessment process, the operation, post-operative care, and the alternatives, benefits and special risks of this surgery.

Living stem cell donations at the Toronto General Hospital have been performed since 2010. There have been no donor deaths, nor have any donors experienced a disabling long-term complication. Detailed information about our program is provided below.

It takes great courage and commitment to change a life through living donation. It is only possible however for approximately 1/3 people who apply to become donors for reasons that will be discussed in this manual. Please read this information carefully and completely. If you decide to pursue living stem cell donation, please complete the Donor Health History Form and submit it to the Living Donor Office, along with proof of your blood type (E.g. a copy of bloodwork done through your family physician or a blood donor card). The Donor Health History Form can be found on our website, [www.UHNtransplant.ca](http://www.UHNtransplant.ca).

## ***Abbreviations***

Deceased donor	DD
Living donor	LD
Keratolimbic Allograft	KLAL
Limbic Stem Cell	LSC

## ***Benefits and Risks for the Transplant Recipient***

Deceased donation is the standard of care for transplantation in Ontario and Canada. The benefits and risks of living donation compared with deceased donation from the recipient's perspective are discussed below.

There are not enough deceased donor tissues to meet the needs of recipients. The waiting time for deceased donor (DD) transplantation ranges from days to months to years, depending on the health status of the recipient.

Keratolimbic Allograft transplant (KLAL) provides the recipient with a high quality stem cells whereas approximately 35% of deceased donor organs may be less than ideal due to advanced donor age, mild to moderate abnormalities and an incomplete knowledge of the donor's health history

KLAL allows recipients to bypass the risks of waiting for a deceased donor graft. After transplantation, the long term outcomes with live donor limbal stem cells (LSC) and deceased donor LSCs are similar.

### ***Principles Guiding the Assessment for Living Stem Cell Donation***

- Donor assessments do not usually start until the recipient has been deemed eligible to receive a living donor transplant. The intended recipient must agree to living donation.
- Becoming a donor is an option for healthy people, over the age of 16. Living donation must be a voluntary choice without external pressure, coercion, or material gain. The donor's primary goal should be to help the recipient. Donors must be able to provide informed consent, have healthy LSCs, and have no major health (psychological, social, or physical) issues.
- **Donor safety is our first priority. We will not rush or compromise the donor assessment process even if the recipient is very sick.**
- Potential donors have a responsibility to honestly and fully report any and all health concerns, issues, and/or behaviors that might affect their candidacy or pose health risks to a potential organ recipient. All information obtained during the assessment is strictly confidential and will not be discussed with anyone other than the donor. If the screening questionnaire reveals major health issues, we may ask the donor to provide consent to obtain reports from their doctor before starting the work-up. It is the donor's responsibility to inform the donor team of any prescription, non-prescription, homeopathic or herbal remedies as these may interfere with donation.
- The duration of work-up is determined by availability of resources, the donor's schedule, the complexity of the donor's health issues, and the time needed to ensure informed consent. It may take days, weeks, or sometimes months to complete all of the necessary tests.
- The possibility of donation will not be offered if the medical and/or surgical team believes that the potential for physical, emotional, or social harm outweighs the benefits. The final decision to perform the living donor transplant rests with the donor's healthcare team.
- The Ontario government pays for the costs of the donor investigations, surgery, and post-discharge care as it does for other forms of health care. Donors who pay into Employment Insurance may be eligible for Employment Insurance Sick Benefits to help with the loss of income while recovering.
- If a potential donor comes from a province other than Ontario, the recipient's OHIP will cover the costs of the donor's medical care at UHN including the evaluation, potential surgery, and post-donation healthcare. On a case-by-case basis, we may arrange for some testing before surgery to be done locally to the donor. Post-donation follow-up care may also be arranged locally as appropriate.
- Our program will consider out-of-country donors on a case-by-case basis. We do not accept donors from countries in circumstances when high quality on-going medical follow-up cannot be guaranteed or when it is difficult to obtain supporting data to confirm that beneficence (doing good) and / or altruism (helping someone else without material gain) are the primary motivations of the donor.

## ***Questions for Potential Living LSC Donors to Consider***

We have developed questions to ask yourself as you consider living donation. Please consider discussing any or all of these issues with members of the Donor Advocate Team as you go through the assessment process.

### *Motivation*

- Have I been totally open with myself about why I want to donate part of my body to the recipient?
- Am I making this decision of my own free will because I believe it is the right choice for both the intended recipient and me?
- Am I considering this surgery because I feel pressured or influenced by others?
- Am I expecting anything in return for my donation? (e.g., Gratitude? Publicity? Other kinds of attention? A better relationship with the recipient?)
- Is my family/personal/professional life relatively stable and secure?
- If not, are there things that I can do now to improve the situation?
- Is there anything I can do now that will improve my recovery? (e.g. lose weight, exercise more, stop smoking).
- Has anyone among my close friends and family shown disapproval or criticized me for wanting to make this donation?
- Will I be able to handle these reactions when I am feeling weak and/or emotionally fragile?

### *Potential Pain and Discomfort*

- Do I feel adequately prepared to deal with the pain and discomfort associated with this surgery?
- Will I be able to communicate my needs – both physical and emotional – to hospital staff and/or my family?
- Can I manage the recovery period without running into problems? (e.g. boredom, anxiety, nervousness)

### *Financial Concerns*

- Am I financially prepared to be away from work for a period of time?
- At what point will I become concerned about my lack of income?
- Do I have an adequate back-up plan in case I need to be off work longer than expected?
- Am I prepared for the possibility that my insurability or employment status may be affected by live donation? (For example, a new condition might be identified during the work-up process or the surgery or a complication could affect your ability to obtain insurance or employment).

### *Post-Donation Concerns*

- Do I have expectations about what this experience will be like for me? Are they realistic?
- Have I thought about how I would feel if the recipient fails to “take care” of the stem cells I donated?
- Have I thought about how I would feel if the recipient has serious complications or the transplant does not work as expected?

*Family Concerns (Other concerns)*

- Have I spoken to my family about how they will cope if I should have serious, unexpected complications?
- Do I have a plan in place for my children and/or dependents if I should have an unexpected outcome?
- Does my family know who my healthcare proxy agent or substitute decision-maker is?
- Do they understand that I have chosen that person to make medical decisions for me if I should become unable to communicate with the medical team?

***The Living Donor Assessment Process***

<b>Overview of the Phases of the Assessment Process</b> <i>(Italics indicate tests and consultations on an as-needed basis)</i>
<b>Phase I: Screening Questionnaire</b> <ul style="list-style-type: none"> <li>- Health history</li> <li>- Blood type compatibility (Must be blood type compatible to proceed to Stage II)</li> <li>- Submit this information to the donor office</li> </ul>
<b>Phase II: Initial Visit</b> <ul style="list-style-type: none"> <li>- Ophthalmology Consult &amp; Surgical Risk Consultation (review of surgical procedure and risks, consent for donation surgery)</li> </ul>
<b>Phase III: Initial Diagnostic Tests</b> <ul style="list-style-type: none"> <li>- Independent medical consult (3<sup>rd</sup> party opinion to determine suitability)</li> <li>- Appointment with donor coordinator</li> <li>- Serology (test for infections)</li> <li>- HLA Tissue Typing (test for compatibility with recipient)</li> <li>- ECG (test for the electrical activity of the heart)</li> <li>- Chest X-ray (image of the lungs)</li> <li>- <i>Echo (if over age 50, if ECG is abnormal, or if pre-existing cardiac history)</i></li> <li>- <i>Exercise Stress Test (if over age 50, if ECG is abnormal, or if pre-existing cardiac history)</i></li> </ul>
<b>Phase IV: Initial Consultations</b> <ul style="list-style-type: none"> <li>- <i>Psychiatry Assessment</i></li> <li>- Social Work (support and financial planning, drug coverage)</li> <li>- <i>Other consults as needed (i.e. hematology, cardiology, etc.)</i></li> </ul>
<b>Phase V: Preparation for Surgery</b> <ul style="list-style-type: none"> <li>- Pre-Operative Education with donor coordinator</li> <li>- Pre-Admission Consultation (Completed by your family doctor)</li> <li>- Schedule surgery date</li> <li>- Final bloodwork completed</li> </ul>

The evaluation process educates donors about the medical, psychosocial and financial implications of donation; determines your suitability (an acceptable medical risk); ensures free (autonomous) informed consent; discusses results of the work-up; provides emotional support and follow-up; and ensures continuity of care throughout the entire donation process.

The assessment process requires donors to plan on attending about 4 different appointments for the tests and consultations. To minimize visits, we try to schedule as many tests as we can in one day. However, completing the assessment process may take up to four hospital visits or more. Donors travelling a long distance to Toronto (out-of-province or out-of-country) should plan a minimum of two trips to Toronto.

We will support you during the work-up process and donors must also advocate for themselves. **If at any point in the assessment process you, your family members, or your friends have any reservations about donation, this information must be shared with the donor team.**

If more than one potential donor volunteers, we will contact the most suitable donor to start assessment. Other donors will be placed “on hold” and will only be contacted if the donor in assessment is deemed unsuitable.

Before undergoing an evaluation, donors should consider the possibility that previously undiagnosed medical conditions may be uncovered during this medical assessment. A new diagnosis could affect your suitability as a donor, your ability to obtain insurance or employment and/or cause emotional distress.

Before starting a work-up, we ask potential donors to confirm that they will be available to undergo the donor surgery within the next 3 months provided that **1)** no contraindications are found and **2)** they still want to proceed after learning more about the procedure.

Both blood type and donor history must be provided prior to proceeding with the donor evaluation. Candidates for LSC donation must be in excellent physical and emotional health. A history of cancer and/or an active infection may be a contraindication to tissue donation. The donor must have normal LSC function. Donors should have family or friends that can provide support before, during and after the surgery. Donors are required to have a family physician.

At any stage the potential donor or the healthcare team may decide that it is inappropriate to proceed with live donation. **Protecting the confidentiality of the donor, recipients are not given information on the reason why a donor is unsuitable.**

**Smoking and the birth control pill are avoidable risk factors for blood clots after surgery, therefore, we ask donors to stop smoking prior to donation. We also ask women using any form of hormonal birth control or replacement therapy to stop this medication and use two alternative forms of contraception before donation. Alcohol and marijuana (and any other recreational or illicit drug use) must be avoided completely for 4 weeks before surgery and for at least 8 weeks after the surgery.**

**Whilst awaiting potential organ donation, donors have a responsibility to avoid all behaviors that would put them at risk for acquiring infections (HIV, HCV, syphilis, etc.) that could be transmitted to the recipient.**

We specifically recommend:

- 1) Abstaining from any high risk behaviors (unprotected sex; intravenous drugs, tattoos, piercings)
- 2) Taking steps to avoid disease transmission through sexual contact (condoms); and
- 3) Avoiding being bitten by mosquitoes, which could transmit the West Nile virus infection, by wearing long sleeve shirts and pants and using mosquito repellent.

If a potential donor does not attend a required test, the test will be re-booked and the donor informed by telephone or e-mail. This will occur twice. If the donor fails to come for the same test three times, a letter will be sent requesting that the donor call the coordinator to re-book. If we do not hear from the donor within two weeks of sending this letter, the donor team will assume that the donor does not wish to proceed with the work-up and the file will be closed. The recipient team will then be informed that the donor is not suitable at this time and that a work-up on an alternate donor can begin.

Potential donors must communicate directly with the team regarding questions and concerns. We do not communicate with third parties or give information to anyone (family members, friends, recipients, etc.) other than the potential donor.

There is a risk of transmitting infections via organ donation. Blood samples are obtained from the donor to confirm normal organ function and test for the presence of several viral diseases including but not limited to Hepatitis B and C, HIV and Syphilis. **Please note that some viruses are reportable by law to the Public Health Department. You may be contacted by Public Health if you have a positive test for these viruses.** Potential donors should immediately report any fever, flu-like illness or neurological symptoms. If a donor has an active infection they cannot donate part of their LSC's because they could transmit this illness to the recipient. To minimize the risk of disease transmission we obtain blood tests to check for infections at the start of the donor assessment and again a few days before the surgery date.

**You can withdraw from the assessment process at any time. The recipient will not be told the reason, only that the donor is deemed unsuitable.**



## *On the Night Before Your Operation*

- Do not eat any food or drink any fluids after midnight (this includes no chewing gum or candy)
- You can drink clear liquids, such as water, apple juice, clear tea or coffee (**with no milk or cream**) up to 5 hours before your surgery.
- You may rinse your mouth and brush your teeth
- **Do not smoke** for 5 hours before your surgery
- **Do not drink any alcohol** for at least 24 hours before your surgery.
- **Stop Aspirin and any blood thinners 5 days prior to surgery**


### **Remove:**

- All nail polish (from your fingers and toes)
- All jewelry and body piercings. (if it is not removed, your operation may be cancelled)
- Leave all jewelry at home, even Medical Alert chains (write this information down and give it to the nurse when you arrive)
- All makeup
- Contact lenses (wear your glasses to the hospital)
- Leave all valuables at home, bring only a small amount of money to the hospital (The hospital is not responsible for lost or stolen items)

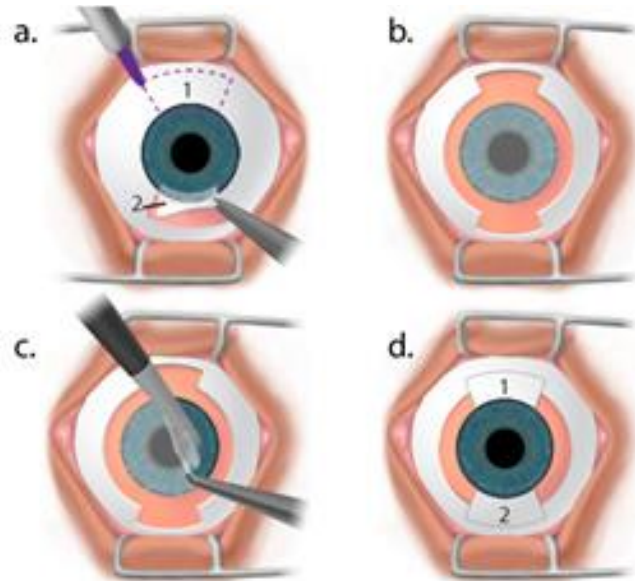
### **What to Bring to the hospital**

- Health card
- All medications you are presently taking, in their original bottles
- Wear loose-fitting clothes and flat shoes
- Hearing aids, dentures and glasses can be worn, but may need to be removed for your operation.

### **On the Day of Your Operation**

- Please arrive at the Toronto Western Hospital at the time written in your package. (You should receive a package in the mail approximately 1 month before the day of your operation).
- In the pre-operative waiting room area, a nurse will put an IV into your arm and check your blood pressure, temperature, pulse and breathing rate.
- The anesthesia doctor or assistant will speak to you about the type of anesthesia you will have (usually local only).
- We will transfer you to the operating room. We give you medication through the IV to help relax.
- We give you eye drops to completely numb (freeze) the eye which will be providing the donor tissue.
- Your ophthalmologist will take 2 small pieces of tissue from the donors' eyes that are about 6 mm by 4 mm. Or, about this size:  This tissue has the limbal stem cells. The tissue is stored in a special solution for the recipient's operation.

- The surgeon closes the wounds with a few stitches or tissue glue and puts antibiotic drops into the eye. The donor may need to wear an eye patch for a few hours or overnight.
- For the recipient's operation, the ophthalmologist will remove any scar tissue over the surface of the cornea.
- Then using a few stitches and/or tissue glue, the ophthalmologist secures the small pieces of donated tissue with the limbal stem cells.
- The surgeon closes the wounds with a few stitches or tissue glue and puts antibiotic drops into the eye. You may need to wear an eye patch for a few hours or overnight



- The donor may experience pain overnight, and may last up to 3-4 days. Pain medication will be prescribed. The pain will completely resolve a few days following surgery. The eye will also be read for 1-3 weeks. This too resolves on its own and does not require additional treatment.

### **On the Morning after Your Operation**

- Your ophthalmologist will examine the operated eye
- It is normal for the eye to be red, feel scratchy or burning, have blurry vision, increased tearing and some eyelid swelling. These symptoms will go away as you heal.

### **1 or 2 Weeks after Your Operation**

- Your ophthalmologist will instruct you when to stop taking your eye drops
- A follow up appointment will be arranged through your ophthalmologist's office.
- Once you have recovered, you may continue to see your local eye specialist for routine eye care.

## ***Surgical Risks and Potential Complications***

Donating your limbal stem cells is considered a routine operation because only a very small area of the surface of the eye is handled (not the inside of the eye ball)

The risks of this operation for the donor include:

- Infection (you will be given antibiotic eye drops)
- Inflammation (you will be given topical steroid eye drops)
- Slower healing of the eye (you may need to wear a bandage contact lens and use more eye drops, or your surgeon may need to sew a transparent special protective thin covering over the eye)
- Nausea or fatigue (caused by the anesthesia at the time of surgery)

**It is very unlikely that a patient can go blind after this operation.**

### ***Potential Expense Reimbursement: PRELOD Program***

This is a Government of Ontario initiative that provides donors with some reimbursement for the costs incurred during the living donor evaluation process. There is limited coverage available for out of province/country donors IF the recipient is an Ontario resident with OHIP. This program does not reimburse the costs of medications. You must provide receipts for submission with the reimbursement claims forms (e.g. parking, food, hotel, travel costs, etc.). More information is available at the Trillium Gift of Life website: <http://www.giftoflife.on.ca/en/transplant.htm>

### ***Social Media and Media Involvement in Living Donation***

As a patient waiting for transplant, you need to consider what, if anything, you would like conveyed regarding social and general media and to inform your loved ones about your choice. Once images and details of your care are posted on a social media site or on the general Internet, you have no control over the information and images.

From time to time, patients use the media and social media to appeal for a donor or for funds to support their transplant expenses. This is entirely up to you, your family and friends. **UHN cannot take part in fundraising or donor appeals for individual patients.** However, please be aware that any media coming into the hospital must first coordinate their request with UHN Public Affairs. UHN will never release confidential information to the media.

For more information or, if you have questions about the use of media and social media as transplant patients, please call Public Affairs & Communications at 416-340-4636.

### *The Next Steps*

Individuals who want to be assessed for living stem cell donation should send the completed and signed **Donor Health History Form** (found at [www.UHNtransplant.ca](http://www.UHNtransplant.ca)) along with documented **proof of your blood type** to the address, or fax number below. The Living Donor Office will contact you and coordinate your assessment. Please let us know if you have any questions.

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