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ST. MICHAEL'S HOSPITAL
A teaching hospital affiliated with the University of Toronto

INFORMED CONSENT FOR ACCEPTANCE OF EXPANDED CRITERIA DONOR KIDNEYS

INTRODUCTION

You have been invited to consider a new kidney donor program for transplantation. We invite you to consider taking participation in a program to better use kidneys recovered from donors with conditions that make it more difficult to efficiently allocate them for transplantation.

Please take your time to make your decision. Discuss it with your family and friends, and please feel free to ask us questions as well. In order to be considered for this program, you must be at least 55 years of age.

It is important that you read this document and understand several general principles that apply to all patients who take part in our Expanded Criteria Donor program.

1. The Expanded Criteria Donor program has been developed by the St. Michael's Hospital Transplant program in collaboration with Trillium Gift of Life of Network of Ontario (TGLN). TGLN coordinates all organ and tissue donation in Ontario.
2. This program does not replace the kidney transplant waiting list already in place; it simply offers a means for some patients to potentially receive a kidney transplant more quickly.
3. Taking part in this program is entirely voluntary.
4. Those participating in this program will still be participating in the regular kidney transplant waiting list program.
5. You may withdraw from the program at any time without having any penalties or loss of waiting time.
6. You are urged to ask any questions you have about this program with the staff members who explain it to you.

WHY IS THIS PROGRAM BEING OFFERED?

Transplantation is beneficial to an increasing number of patients with kidney failure. However, there is a serious shortage of deceased donor kidneys which are kidneys recovered from someone who died. The waiting list in Canada increases by more than 100 patients each year and this year, over 100 patients will die waiting for a kidney transplant. The waiting time for a deceased donor kidney in the Greater Toronto Area is between 7-11 years.

One way to increase the number of deceased donor kidneys is to use the Expanded Criteria Donors. The Expanded Criteria Donors are donors who are older or who have specific health problems that might affect how well and how long their kidneys will work after they are transplanted.

This new Expanded Criteria Donor program will allow the St. Michael's Hospital transplant program to use these kidneys in recipients who are facing very long waiting times, and who would be willing to accept a kidney of lesser quality in order to perhaps receive a transplant faster.

A study done by the United States National Kidney Program showed that patients receiving Expanded Criteria Donor kidneys add about five extra years to their life compared to those not receiving a transplant and remaining on dialysis.

You are being told about this program because you have kidney failure, you do not have a potential living kidney donor and given your age and overall condition, you might possibly receive significant benefit from an Expanded Criteria Donor kidney.

WHAT IS INVOLVED IN THE PROGRAM?

To take part in the program, you will be asked to sign this informed consent document. You will have all the medical tests and procedures that are part of the regular recipient medical workup whether or not you enroll in this program.

Kidneys from Expanded Criteria Donors will be offered first to patients who have consented in advance to be considered for them, and will be offered to the compatible patient waiting the longest on the list. This program will place the kidneys from donors who generally meet the following guidelines:

1. All donors 60 years of age or older are considered Expanded Criteria Donors.
2. All donors between the ages of 50-59 years of age who have two or more of the following criteria:
 - I. the donor died from a stroke or cerebrovascular accident
 - II. the donor had a medical history of hypertension (high blood pressure)
 - III. the donor's most recent creatinine clearance was 60-80 ml/ min. Creatinine clearance is a measure of how well the kidney works; normal values typically range from 80-120 ml/min.

Please note that these are guidelines only. Actual selection of donors will continue to take place on a case-by-case basis.

WHAT ARE THE RISKS OF ACCEPTING AN EXPANDED CRITERIA DONOR KIDNEY?

You may require more frequent biopsies of the transplanted kidney to assess kidney function and potential rejection episodes after the transplant.

After the transplant, the kidney may be slow to start working. As a result, you may require dialysis for a period of time after the transplant. **Long-term kidney function may be less than that from a non-Expanded Criteria Donor kidney.**

There is a rare possibility that the kidney will not work at all after the transplant. The risk of the kidney transplant not working at all is slightly higher for patients that receive an Expanded Criteria Donor kidney.

ARE THERE ANY BENEFITS TO TAKING PART IN THIS PROGRAM?

The main benefit of participating in the Expanded Criteria Donor program would be to shorten the time you wait for a kidney transplant. Recent analysis of transplant data showed that the longer you wait on dialysis for a transplant, the poorer the transplant outcome.

WHAT OTHER OPTIONS ARE THERE?

Remember, you will still be listed on the regular kidney transplant waiting list and do not lose your place by entering or withdrawing from this program. You may also decline to enroll in this program. Your other option would be a living donor transplant from a family member or friend.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in the Expanded Criteria Donor program is entirely voluntary. You may choose not to participate in or withdraw from the program at any time. If so, your regular care will not be affected in any way and you will not lose any of the benefits you would normally receive. As we mentioned earlier, you would not lose your place on the regular transplant waiting list. We will try to keep you informed of any new developments pertaining to this program.

WHO DO I CALL IF I HAVE ANY QUESTIONS OR PROBLEMS?

For questions about the program, contact your pre-transplant coordinator or your transplant physician by calling:

St. Michael's Hospital Renal Transplant Program
(416) 867-7460 X8179 or 416-867-7460 X8436

PATIENT SIGNATURE

I, the undersigned, have been informed about the Extended Criteria Donor program's purpose, procedures, possible benefits and risks, and I have received a copy of this consent document. I have been given the opportunity to ask question. I have been told I can ask questions in the future. I voluntarily agree to participate in this program. I am free to withdraw from the program at any time without need to justify my decision. A withdrawal will not in any way affect my place on the regular transplant waiting list, future treatment or medical management.

PRINTED NAME

SIGNATURE

DATE

STAFF OBTAINING INFORMED CONSENT SIGNATURE

As a representative of the Extended Criteria Donor program, I have explained the purpose, the procedures, the benefits and the risks that are involved in this program. To my knowledge, any questions that have been raised have been answered to the patient's satisfaction.

PERSON OBTAINING CONSENT

TITLE

SIGNATURE

DATE

Please return by mail or fax.

MAIL TO:

FAX : 416-867-3678

St. Michael's Hospital
Renal Transplant Program
Attention: Meriam Jayoma-Austria
61 Queen Street East, 9th Floor
Toronto, Ontario M5C 2T2