



*California Pacific  
Medical Center*

A Sutter Health Affiliate

Community Based, Not For Profit

*Department of Transplantation  
Kidney and Pancreas Transplant Program*

## **EXTENDED CRITERIA DONOR CONSENT FORM**

### **SUMMARY**

Donors:

- Over age 50 with any two of the following:
  - History of high blood pressure.
  - Stroke as cause of brain death.
  - Elevated creatinine level.
- Any donor over age 60.

Recipients:

- Patients over age 58.
- Diabetic patients over age 40.
- Any patients doing poorly on dialysis.

Advantages: Shorter wait until transplant.

Disadvantages: Success rate may be lower.

### **INTRODUCTION**

We invite you to take part in a program to better use kidneys recovered from donors with conditions that make it more difficult to efficiently place them for transplantation. Please take your time to make your decision. It is important to discuss it with your family and friends. Also, please feel free to ask the Kidney Team questions. This program will not be recommended for all of our patients. It is important that you read this document and understand several general principles that apply to all who take part in the expanded criteria donor program.

1. This program has been developed by the Organ Procurement and Transplant Network, the organization that manages the national patient waiting list.
2. This program does not replace the waiting list already in place; it simply offers a means for some patients to receive a 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 waiting list program for the kidneys distributed through that listing.
5. You may withdraw from the program at any time without incurring penalties or loss of waiting time points.
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?**

There is a serious shortage of deceased donor kidneys (kidneys recovered from someone who died) while, at the same time, transplantation is beneficial to an increasing number of patients with kidney failure. The waiting list increases by several thousand each year and more than 4,000 patients will die waiting for a kidney transplant this year. The waiting time for a cadaver kidney is over four years in most parts of the country.

One way to increase the number of cadaver kidneys is to use “extended criteria” donors. These 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. Many of these kidneys are already being transplanted, but a large number are discarded when the time to get them transplanted is too long, resulting in too much damage. This new program allows transplant centers to use these kidneys locally, without having to go entirely through the national system. We believe this will help those kidneys to perform better and provide adequate function for the recipients to stop dialysis. A study done by a national kidney program showed that patients receiving these kidneys add about five extra years to their life compared to 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 you age and overall condition, you might 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. Kidneys from expanded criteria donors will be offered only to patients who have agreed in advance to be considered for them. They will be offered first to anyone on this list who is a perfect match. If there is no perfect match, then they will be offered to the compatible patient waiting the longest on the list. The kidneys from donors who meet the following criteria will be placed by this program:

- All donors 60 or older;
- All donors between ages 50 to 59 who have two or more of the following:
  - (1) The donor died from a stroke or cerebrovascular accident;
  - (2) The donor had a medical history of hypertension (high blood pressure);

(3) and/or the donor's most recent creatinine was 1.5 mg/dl or greater (creatinine is a measure of how well the kidney works; normal values typically range from 0.6 mg/dl to 1.2 mg/dl).

### **WHAT ARE THE POTENTIAL RISKS TO TAKING PART IN THIS PROGRAM?**

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. You may require more frequent biopsies of the transplanted kidney to assess for kidney function and potential rejection episodes after the transplant. You may require dialysis for a short period of time after the transplant. Long-term kidney function may be less than that from a non-expanded criteria donor kidney.

### **ARE THERE ANY BENEFITS TO TAKING PART IN THIS PROGRAM?**

The main benefit would be to shorten the time you wait for a kidney transplant. Recent analysis of transplant data shows 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 waiting list for a non-expanded donor kidney. 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 THE COSTS?**

You or your insurance company will be charged for the continuing medical care and/or hospitalization that are part of the kidney transplant procedure. There are no expected additional or special costs that are part of the expanded criteria kidney donor program.

### **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this program is voluntary. You may choose not to take part in or to leave the program at any time. If so, your regular care will not be affected and you will not lose any of the benefits you would normally receive. 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, 415-600-1000, or your transplant physician, 415-600-1061.

**SIGNATURES**

I, the undersigned, have been informed about this 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 questions and I have been told that I can ask questions in the future.

I voluntarily (*initial one below*):

\_\_\_\_\_ agree

\_\_\_\_\_ do not 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 future treatment or medical management.

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Date