

## **CONSENT TO REGISTER A PERSON WAITING FOR A KIDNEY - WILLING TO CROSS (WTC) PROGRAM**

### **Introduction**

You are invited to participate in a new Canadian “Willing to Cross” (WTC) Program. This program is designed to improve the chances of finding a kidney for people on the waiting list who have a high number of antibodies against histocompatibility antigens (HLA).

### **Background**

The immune system can produce antibodies against foreign molecules called human leukocyte antigens (HLA). This phenomenon, called sensitization, can happen through pregnancy, blood transfusion, or following organ transplants. In the context of transplantation, if these antibodies bind to the donor organ, they can lead to rejection and kidney injury. Thus, in Canada we only perform kidney transplantation when the patient has no detectable antibodies against the donor. This practice prevents rejection, but increases the waiting time before finding a compatible kidney for people who have a lot of antibodies. These people may remain on dialysis for a long time and develop dialysis-related complications while they wait.

To address this issue, Canadian Blood Services (CBS) launched a national program called “Willing to Cross” (WTC) to help people on the waiting list who have antibody levels of 99 % or higher, making them compatible with less than 1 % of the population. Under this program, people on the waiting list can receive a kidney from a donor against whom they have antibodies, if these antibodies are determined to be low-risk by their physician according to established criteria. This assessment is made after a detailed review of the chart and discussions with the laboratory specialist who measures HLA antibodies.

The risk of rejection in the context of the WTC Program is unknown, but it is expected to be somewhat higher than standard kidney transplantation. People participating in this program will receive additional safety monitoring beyond standard-of-care. This includes regular blood draws to monitor antibody levels. In addition, those people will have a kidney biopsy 3 months after transplantation to detect early signs of rejection that may be missed on blood tests, allowing for prompt treatment.

The safety of this new program is closely monitored by CBS to ensure the outcomes for those waiting and undergoing transplants are in line with the expected benefits.

### **Your participation is voluntary**

Your participation is entirely voluntary. You have the right to refuse to participate in this clinical program. If you decide to participate, you can choose to withdraw from the program at any time without any negative consequences on the medical care or other services you may receive. If you decline to participate in the Willing to Cross Program, you will continue to remain active in the Canadian Highly Sensitized Program, which allows you to receive a matched kidney from anywhere in Canada.

Extra Surveillance Testing Required by the WTC Program are:

1. An HLA antibody screening test (blood tests) during the first and second weeks after transplantation, as well as 1 month, 3 months, 6 months, and 1 year after transplantation, then once a year.
2. A surveillance kidney biopsy 3 months after transplantation.

In the event rejection occurs due to antibodies, your care team will develop a treatment plan based on what is best for your specific situation. The side effects of medications will be discussed with you in detail. You may need treatment with plasmapheresis, a procedure similar to hemodialysis, which involves removing the antibodies causing rejection from your blood. In addition, you may receive intravenous medications that target immune cells making the harmful antibodies. These anti-rejection medications tend to weaken the immune system and may increase the risk of infection and developing cancers.



- I have read (alone or with assistance) and understand this consent form;
- I understand the benefits and potential risks associated with the Willing to Cross (WTC) Program and agree to participate;
- I was able to ask questions and I received explanations regarding this document.

**I have explained this consent form and I have answered all the signatory's questions.**

Your personal information will be kept at Transplant Québec's office, located at 4100 Molson Street, Suite 200, Montreal, Quebec, H1Y 3N1. In order to exercise your right to access and rectify your personal information, please contact us at [vueprivee@transplantquebec.ca](mailto:vueprivee@transplantquebec.ca). Only Transplant Québec employees who need to consult your personal information in the course of their duties will be given access to it.