

Patient Acknowledgement for Kidney, Pancreas or Kidney-Pancreas Transplantation

This form provides information about having a kidney transplant. It describes the purpose, process, tests, risks, benefits, and alternatives.

Be sure to read the entire form even though the transplant team may have talked with you about some of the issues covered in it. We want to be sure that you:

- Understand all the issues discussed in the form.
- Read all the handouts you have received about having an Intestine transplant.
- Ask questions, if you have any doubts or concerns.
- Ask for more written information, if you want it.

After you have read this form and have had all of your questions answered:

- Put your initials at the bottom of each page.
- Sign the last page if you wish to proceed with the transplant work-up.

You may change your mind and withdraw your decision to proceed at any time prior to the transplant.

Your signature on this form does not guarantee that you will be placed on the waiting list or receive a transplant.

Evaluation Process

A thorough evaluation is done to find out if a transplant is the best treatment option for you. After the evaluation is done you may or may not be placed on the waiting list. You will be given a handout with details about the selection criteria for a transplant.

The evaluation may reveal conditions that need to be corrected prior to listing for transplant surgery. It could also reveal conditions that would make the transplant surgery a poor choice. If we discover that you have conditions other than kidney failure that will affect the success of the transplantation we may refer you to your primary doctor or another health care provider. You may have the condition checked further and/or treated at UWMC. Be sure to check with your insurance company as care for the new problem may or may not be covered.

The evaluation for a kidney, pancreas, or kidney-pancreas transplant includes many tests, procedures, and visits with doctors. It also includes meeting with many members of the transplant team. It helps us to know if:

- Transplant is the right treatment for you.
- You are well enough to have transplant surgery.
- There is any other treatment besides a transplant that can help you.

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Transplant Team Members

- The **Transplant Coordinator** provides education about the transplant work-up process, listing for transplant and patient responsibilities before and after transplant. The coordinator is your advocate throughout the transplant process and will work with you to ensure all your needs are met. Meeting with the coordinator is intended to provide you with an opportunity to ask questions and to become fully informed about the transplant process.
- A **Transplant Nephrologist** meets with you and determines if you are a good medical candidate for transplant. They will review your medical history and assess your current kidney function. They will also check on the status of your heart and blood vessels supplying the heart, brain, and legs.
- A **Transplant Surgeon** meets with you to discuss whether a transplant is an option for you, based on the results of your work up. The surgeon will also discuss the significance of having the surgery, the transplant procedure itself, the risks of the surgery and the possible complications after your transplant and during the recovery phase.
- A **Social Worker** meets with you to evaluate your ability to cope with the stress of having a transplant and to follow a complex treatment plan, both before and after surgery. The social worker also helps to identify your support network.
- A **Financial Coordinator** will talk to you about the costs associated with your transplant and the medications you will require after transplant. They will work with you to help you understand your insurance coverage and the costs that may not be covered by insurance.
- A **Psychiatrist/Psychologist** may conduct a more in-depth psychiatric evaluation and assessment. Some patients with a history of drug or alcohol abuse may be required to participate in a rehabilitation program and/or to abstain from substance use prior to and after transplant listing.
- A **Dietitian** performs an assessment of your diet and provides education about nutrition.
- Some patients may be referred to another service for consultation. For example, many patients need to be seen by a hepatologist (liver doctor), pulmonologist (lung doctor), urologist (bladder doctor), or a cardiologist (heart doctor) or infection disease specialist or oncologist (cancer specialist) to assess for other medical conditions.

After your transplant clinic visit, the transplant team will discuss your transplant candidacy. The team will determine which doctors you should see and what medical tests should be performed as part of your evaluation process to make sure that you do not have infections, blood vessel problems, or a cancer that would make transplant dangerous for you.

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Evaluation Testing

Many different tests are done to determine if you are a suitable transplant recipient. Some of the following tests may be included in your evaluation process. Remember, other tests may need to be done based on the results of these tests.

- **Blood tests** help to determine your current level of kidney function or response to dialysis treatments. Tests are done to determine your blood and HLA type for organ matching and screen for exposure to infections, including HIV. Other tests may be done to determine how well other organs are functioning, your blood counts, and how well your clotting system is working. Sometimes test will be done to determine if the disease that caused your kidneys to fail is still active.
- A **chest X-ray** helps your doctor identify any problems with your lungs.
- A **urine test** (when possible) is done to screen for urinary tract diseases as well as drugs and alcohol in your system.
- An **EKG, echocardiogram** and/or **stress test** shows your heart rhythm, function of your heart valves and muscle and effectiveness of your heart as a pump. This helps your doctors to decide if your heart function is strong enough for transplant surgery, or if additional cardiac testing and treatment is needed. If you have diabetes your risk for heart disease is higher. It is very likely that you will be asked to have a stress test. These test results may indicate need for you to have a heart angiogram.
- **Pulmonary function tests (breathing tests)** may be required if you have a history of smoking, asthma, or lung disease.
- **Pap smear, mammogram, and/or prostate-specific antigen (PSA) blood test and colonoscopy** are general health and cancer screening tests that are done based on your age, gender, and family history.
- **Doppler studies:** Assess the blood flow to the brain and legs.
- **CT Scan:** Assess the thickness and calcification of the blood vessels and size of your kidneys in some patients.
- **Imaging of the abdomen and liver biopsy** are done if you have hepatitis B or C.

Selection Committee

After the evaluation is done, your case will be presented to the UWMC Kidney/Pancreas Transplant Selection Committee. The committee will decide if you are a candidate for a transplant. You must be

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medically suitable to undergo the transplant procedure and be expected to survive for a reasonable length of time after the transplant. You must show that you have the social, financial, and support resources to be able to follow the complex medical care plan required for transplant patients. The committee will decide:

- 1) To accept you for placement on the Kidney transplant waiting list.
- 2) Not to accept you for placement on the waiting list and explain why you were not accepted.
- 3) To schedule more visits and tests before they make a decision.

The committee will send you a letter about their decision within 10 business days of your presentation to the committee.

Kidney, pancreas, or kidney and pancreas transplants improve quality of life and prolongs life. However, the potential benefits do not result from surgery alone. They also depend on your efforts to follow the complex treatment plan prescribed by your doctors. The treatment plan also comes with risks due to surgery and the medicine needed to keep your body from rejecting the transplant. The risks are infection, diabetes and cancer.

It is important for you to be aware of potential risks and complications as they can result in serious injury and death.

Organ Allocation to the Transplant List

Organs from deceased donors are allocated according to the policy of United Network for Organ Sharing (UNOS). Every time there is a potential donor, a new list is generated based on time on dialysis or waiting list, age (pediatric recipients get preference), and how many antibodies your blood has in it against possible donors. The closer the genetic match and the longer the recipient is on the waiting list or dialysis, the higher the recipient's place is on the list. All patients must undergo a final crossmatch, which is when we test the actual donor's tissue with a sample of your blood. The crossmatch must be negative (no bad reaction) for us to proceed with the transplant.

Living Donor Transplantation

Living donation of a kidney (when a healthy relative or friend donates one of their kidneys) is the best treatment option for transplant candidates. With a living donor we can precede with the transplant much sooner (avoiding the complications of dialysis) and the kidney works immediately having a longer life. Your doctors will talk with you about this option. It is also important to know that non-related persons can also be living kidney donors. Healthy volunteers with compatible blood type should be considered for living donation. If your donor is not matching with you from blood type or positive crossmatch they can participate in kidney exchange program with similar donors of other recipients.

When a deceased donor organ becomes available, you will be called, and you must be ready to come to the hospital right away. If the organ comes from a donor with risk factors, or donation after cardiac death, your surgeon will review this with you and assist you in making your decision. It is at this point that the surgeon has a clear picture of the risks associated with this organ versus the risk of waiting for the next available

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donor. You have the option to decline an organ. If the organ is determined to be unusable once we see it or the crossmatch is positive, you will be discharged home, but you will remain on the waiting list.

During the transplant surgery you will be put under general anesthesia, which means you will be given medications to put you to sleep, block pain, and paralyze parts of your body. You will also be placed on a machine to help you breathe. The anesthesiologist will also talk with you in more detail about the risks of anesthesia.

The transplant surgeon will make an incision in your abdomen and will usually place the kidney into your lower left or right side of your abdomen. Generally, your native kidneys will not be removed. Those who are also receiving a pancreas transplant will have the pancreas placed in the opposite side of the abdomen. The scar may be either in the middle of your abdomen or at the very lower part of the abdomen. The surgeon will talk with you to determine this on the day of the surgery.

You will be in the operating room about 3 to 4 hours. Drains will be put into your body to allow fluids to be removed and to help you heal. A urine drainage tube will be placed in your bladder and remain for the first days after transplant.

Care and Recovery after Surgery

After the surgery you will be taken to the Transplant Unit where you will be watched closely. Special devices called intermittent pressure boots or sleeves (also called sequential compression devices) will be placed around your legs to prevent blood clots.

You will have pain after the surgery. You will be asked about your pain level and you will receive several medications to help control your pain. Most transplant recipients have a significant reduction in the pain 2 to 3 days after surgery.

Your blood sugars may be elevated after surgery even if you do not have diabetes. If this happens you will be on an insulin and glucose infusion. If you have a pancreas transplant your blood sugar will be checked every 1 to 2 hours.

Your length of stay in the hospital will depend on the rate of your recovery and the type of transplant you have. The length of your hospital stay also depends on the severity of your illness prior to transplant and/or complications after surgery. If your new kidney is functioning, your will go home without dialysis. If it is slow to function, you will go home on dialysis. You will be seen in the clinic to determine the correct time to stop dialysis. This usually occurs within 3 weeks from the transplant.

After you leave the hospital, you will still be recovering. For the first 4 to 6 weeks, you will have some limitations on your daily activities, based on your unique needs. If you have any complications after surgery your recovery time may be longer. During the recovery period the transplant team will follow your progress. Your follow-up visits 2 to 3 times per week will include exams, lab tests, and scans of your abdomen to see

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how well your transplanted kidney is working. Biopsies may be done on a routine basis and as needed to diagnose possible complications, including rejection, infection, or recurrent kidney disease.

The transplant team will follow you often for 3 to 6 months after transplant. Once you are stable, usually between 1 to 3 months after transplant, your care will be transitioned back to your primary nephrologist. If you have received a pancreas transplant you may be followed at our transplant clinic for up to 6 months after surgery. After you are back with your nephrologist you will still be followed periodically at our transplant clinic. For most patients during the first year, this is every 3 months. After the first year, the visits are annually. Patients who develop complications may need to be seen more often by transplant team. No matter your condition, once you are more than one year from your surgery you will need to have lab testing done every 1 to 2 months for the rest of your life. This helps to identify problems early so that treatment may be started and be more effective.

Alternative Treatments

Several studies have shown that transplant is the best treatment for patients with chronic renal failure. Alternative treatment such as dialysis is available for your medical condition. The dialysis treatments available include hemodialysis at a dialysis center, home peritoneal dialysis and home hemodialysis. Peritoneal dialysis may be done from time to time throughout the day or overnight with cycling machine. Home hemodialysis may be done with different types of machines based on the type of dialysis -short daily or nightly.

New studies show that daily nighttime dialysis may provide the same patient survival benefit as a deceased donor kidney transplant. However, this dialysis treatment is not available in all locations. Talk with a member of your health care team about your condition and possible alternative therapies for your condition.

There are risks in all surgeries, especially those that are done using general anesthesia. Many complications are minor and get better on their own. In some cases, they are serious enough to require another surgery or medical procedure. You can die from the operation or complications associated with the transplant procedure and medications.

Some patients develop wound infections after transplant. This is minimized by giving antibiotics at the time of surgery for kidney and pancreas recipients and for up to 24 hours after surgery for pancreas recipients. Also, oral antibiotics are given to decrease the risk of wound infection and urinary tract (bladder) infection. Sometimes, pancreas transplant recipients have drainage from their wound caused by the proteins secreted by the pancreas. If this develops you will be watched carefully by the surgeon. Healing takes about 1 to 2 months.

Patients are at an increased risk for bleeding because they are in kidney failure, though it is not common to require a blood transfusion. Technical issues can also happen, including kidney artery or vein thrombosis in a small percentage of patients. This is a clot that develops in one of the major blood vessels going to or from your kidney. Should this happen, you will require another operation; sometime the kidney needs to be removed and dialysis restarted. There is the same risk for clotting with a pancreas transplant. If this happens it is removed.

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Some patients have urine tube complications such as leaks and strictures (narrowing). Many urine leaks get better without the need for surgery. Sometimes, tubes need to be placed through the skin to aid in the healing process. In some cases, surgery is needed to correct the urine leak. Sometimes the leak involves lymph fluid and if the collection of fluid gets big enough to push on the kidney, then a drainage procedure or operation is needed. Somewhat more common is the issue of ureteral (urine tube) strictures. A ureteral stricture is a narrowing of the tube that drains the urine from the kidney into the bladder. Some of the strictures can be repaired by non-surgical means such as insertion of tubes and stents, but some will require surgical repair.

If a leak from the pancreas transplant connection to the bowel happens you might need another operation to fix it. In this case there is also a risk for a serious abdominal infection, so drains may be needed after the surgery to treat the infection.

Some patients have a stent placed between the transplant kidney and the bladder to keep the passageway open for urine to flow through. This stent is not permanent and will be removed about 6 weeks after transplant.

There may be a delay in the function of your transplanted kidney. Such a delay may increase the length of your hospital stay and increase the risk of other complications. If there is delayed function of your transplanted kidney you may return home on dialysis. Dialysis will be performed after the transplant. Before every dialysis you will be checked by the transplant nephrologist to see if the treatment is truly needed.

The need for dialysis, or not feeling better right after transplant, may lead to depression. Also, your energy may not return right away. That will take time, exercise, and getting the right mix of medications. Also, your family and social support structure may change. Finances may change and you may need to talk with the social worker about this. Your plan for covering medications in the long run will need to be talked over with the pharmacist, coordinator, and social worker. Your job requirements, such as potential for exposure to infections and travel should be discussed with your doctor, coordinator, and social worker. Every effort will be made to help you maintain your current job, or if you do not have one, to encourage you to find one.

Potential Long-Term Medical Risks

On average, deceased donor kidney transplants last about 12 years. Kidneys from living donors generally last an average of 18 years. In some cases, the original disease comes back after transplant or patients develop chronic rejection. Some kidney transplants fail from infections in the kidney and some from medication side effects. Sometimes, a second transplant may be done, but usually patients go back on dialysis first. Some patients may not be appropriate candidates for a second transplant.

Rarely, the deceased donor kidney does not work from the start. If this happens then you would be put back on the transplant list with all the priority that you had before you had the transplant. In other words, you would not put at the end of the line, but back in line where you were before.

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Pancreas transplants may reject. The only way to know is to check certain blood tests routinely. Also, the pancreas transplant is more susceptible to clotting off. It can clot off if you lose excessive amounts of fluid with illnesses causing nausea, vomiting, and /or diarrhea. Be sure to check in with your primary health team or call UWMC Transplant Services if you have a severe illness. They can give you advice about how to manage your care.

There are other risks associated with kidney and pancreas transplants. Infections from bacteria, viruses, or fungi, acute rejection, and side-effects from drugs that suppress the immune system are all possible complications. Side-effects from immune-suppressing drugs include kidney problems, gastrointestinal complaints, blood count abnormalities, nerve damage, high blood pressure, weight gain, diabetes, and others. There may be a need for repeated kidney biopsies, surgeries, and other procedures.

If you are overweight, over 40 years old, and have a family history of diabetes that starts in adulthood you are at increased risk of developing diabetes after transplant. You should think about this before transplant and minimize your risk by exercising and eating right. You should be at the proper weight for you as determined by the dietitian.

There is a slight increase in the risk of certain kinds of cancer (including skin cancer and post-transplant lymphoproliferative diseases or lymphoma) because of the medicines you take to suppress your immune system to prevent rejection. Other common cancers, such as breast, cervical and colon may occur more often. You will need to keep your cancer screenings up to date after the transplant.

Miscellaneous Risks

Despite the use of compression boots, blood clots may develop in the legs and break free and move through the heart to the lungs. In the lungs, they can interfere with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period.

The risk of infection is higher for transplant recipients than other surgical patients. This is because the treatments needed to prevent organ rejection make the body less capable of fighting infection. The abdominal incision for the kidney transplant is a potential site for infection. Infections in the sites where tubes are placed in your body (to help you breathe, to provide fluids (IV) and/or nutrition, and to monitor body functions) can cause pneumonia, blood in your bladder (Foley), and skin infections.

Damage to nerves may occur. This can happen from direct contact within the abdomen or from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis, and/or pain. In most cases these symptoms are temporary, but in rare cases they can last for long periods or even become permanent.

Nerve damage and bleeding in the eyes can occur after pancreas surgery from a rapid normalization of the blood sugar. This means that if you have diabetes and are on the list for a pancreas transplant you need to try to keep your blood sugar as under control as possible.

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Other possible complications include: injury to structures in the abdomen, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, pneumonia, heart attack, stroke, and permanent scarring at the site of the abdominal incision.

National and Transplant Center-Specific Outcomes

Statistics about survival after kidney transplant are available from the Scientific Registry of Transplant Recipients (SRTR). We will give you a handout with details about these statistics. You can also review these statistics at www.ustransplant.org.

Statistics for UWMC meet or exceed these standards. They do not differ significantly from the expected survival rates.

Notification of Medicare Outcome Requirements not being met by Center Specific outcome requirements need to be met by transplant centers: We are required to notify you if we do not meet those requirements. At this time, the University of Washington Medical Center meets all requirements for transplant centers.

With increasing numbers of people waiting for kidney transplants, there is an urgent need to consider and use all possible donor organs **especially when there is no living kidney donor available**. Currently the young and healthy deceased donors are decreasing. The donor quality is assessed by evaluating factors (age, height, weight, medical conditions, cause and type of death etc.) of the deceased donor (KDPI – Kidney Donor Profile Index). Certain conditions in the donor will affect the long-term outcome of your transplant such as the donor’s history and medical conditions of the donor, the condition of the organ when retrieved from the donor. The benefit of using the potential kidneys outweighs the risk of remaining on dialysis namely complications of renal failure and death.

The risk criteria for transmission of blood borne infection are assessed during donor evaluation with history from the family or available medical records as per the PHS guidelines (2020) (eg: IV drug use for nonmedical reasons, sexual risk factors, unknown history and death during incarceration.)

All the donors are tested for hepatitis viruses (B and C) and HIV virus with very sensitive tests. Chances of infection transmission to the recipient are extremely low if the tests for the viruses are negative. You will only be offered kidneys from donors with negative virus tests. If you are offered an organ from a virus positive donor you will need to sign a consent form after appropriate counseling (this is for hep C+ donors). The risk for undetected HIV, HBV, and HCB infection is very low but not zero; should transmission occur, effective therapies are available. Proceeding with transplant using kidneys with risk criteria will be discussed in detail during your evaluation phase, organ offer period and transplant admission. Importantly, accepting organs from donors with risk criteria will increase the chance for survival.

Recipient testing mandate for Hepatitis B, C and HIV viruses before and after transplantation:

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In compliance with the recent PHS guidelines (June 26, 2020) for the monitoring of transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection.

- You will be tested on transplant admission, prior to receiving the organ (Irrespective of the type of donor) for:
 - HIV antigen/antibody
 - HBV surface antibody, surface antigen, and core antibody, and
 - HCV antibody and nucleic acid testing (NAT)
- You also will be tested at 4-6 weeks post-transplant for:
 - HIV antigen/antibody – with reflexive NAT if positive
 - HBV NAT
 - HCV NAT

Right to Refuse Transplant

You have the choice not to have a transplant. If you choose not to have a transplant, treatment for your kidney disease will continue. You have the right to refuse an organ. If you do refuse a particular organ, you will not lose your place on the list. However, repeated refusals to accept healthy organs may indicate that you do not want a transplant and that you should be removed from the waiting list. If you are in otherwise good condition (such as no medical reason to pass on the transplant) for kidney transplant and you refuse two organ offers you will be taken off the list. After the first refusal you will be contacted by the coordinator and social worker to discuss your thoughts about and enthusiasm for transplant. You may be asked to come back to the transplant center for a visit to re-evaluate your transplant candidacy. If you do not have transplant surgery, your condition is likely to worsen and limit your life expectancy. However, transplant is a treatment, not a cure, and we want to make sure that you are comfortable with this treatment.

If There Are Changes in Your Situation

Once you are on the waiting list, it is expected that you will be prepared for the transplant when it becomes available. Kidney transplants are not scheduled procedures, so they can occur at any time. Please call your transplant coordinator right away if there are changes in your:

- Medical Condition
- Financial/Insurance situation
- Caregiver/Support system
- Living arrangements
- Transportation plan
- Any other part of your transplant-related support

Changes in your life may affect your candidacy for transplant and could result in your listing status being changed to “temporarily inactive” while the situation is resolved or removal from the waiting list. The transplant team will support you in your efforts to resolve these situations.

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Some patients have travel plans or other events that they wish to participate in while they are awaiting transplant. Patients can request to be made “temporarily inactive” on the waiting list for such situations. Be sure to talk with your transplant coordinator if you want to make this type of request. It is possible that you may miss a transplant opportunity during this time.

Notification to Patient Regarding Medicare Center Approval

According to regulatory guidelines, if at any time the program’s Medicare approval is terminated, either voluntarily or involuntarily, the center will notify all patients associated with the program within 30 days prior to approval being terminated.

Transplantation by a Transplant Center Not Approved by Medicare

If you have your transplant at a facility that is not approved by Medicare for transplantation, your ability to have your immunosuppressive drugs paid for under Medicare Part B could be affected. University of Washington Medical Center is an approved facility.

After you have a kidney transplant, health insurance companies may consider you to have a pre-existing condition and refuse payment for medical care, treatments or procedures. After the surgery, your health insurance and life insurance premiums may increase and remain higher. In the future, insurance companies could refuse to insure you.

Notification of Transplant Program Inactivation (Closure)

If any event were to occur that might impact our ability to provide transplant services, our staff will attempt to contact you regarding the type of program inactivation (closure). This would be rare, but may include lack of required physician coverage, operational changes requiring temporary cessation of transplantation, or a natural disaster. The inactivation may be short-term or long-term.

Our program directors and administrator will initiate necessary notification of inactivation in a timely manner. If the event is unplanned, the center’s disaster call list will be initiated once inactivation is determined. The designated individual(s) would initiate notification to patients. We would use whatever means available to contact you, such as telephone, email, text, or mail. If the disaster is severe, we will make arrangements for an out-of-hospital agency to assist us with the notification.

Waiting Time Transfer and Multiple Listing

If listed for transplant, you have the option of being listed for transplant at multiple transplant centers that are not in the same UNOS region, and the ability to transfer your waiting time to a different transplant center without loss of your waiting time.

Concerns or Grievances

The United Network for Organ Sharing provides a toll-free patient services line to help transplant candidates, recipients, living donors, and family members understand organ allocation practices and transplant related data. You may also call this number to discuss a problem you may be having with your

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transplant center or the transplantation system in general. The toll-free patient services line number is 888-894-6361.

Program Coverage Plan

In compliance with UNOS Bylaws, the University of Washington Medical Center has established on-call coverage plan which provides coverages for liver/kidney/transplant programs, including transplant surgeon and transplant physician support and availability for 365 a year, 24 hours a day, and 7 days a week. This 24 hour/7 day a week schedule provides for a transplant surgeon and a transplant physician to be on the premises within one hour ground transportation time to address urgent patient issues and facilitate organ acceptance, procurement, and implantation.

I have received this information from the transplant team. I have read the information and been able to ask questions. I understand the information that has been given to me.

Signature
Patient or Legal Next of Kin

Printed Name

Date:

Signature
Transplant Nurse Coordinator

Printed Name

Date:

Signature
Transplant Physician

Printed Name

Date:

Patient Initials

PT.NO

NAME

DOB

UW Medicine
Harborview Medical Center – UW Medical Center
University of Washington Physicians
Seattle, Washington

**KIDNEY AND/OR PANCREAS TRANSPLANT – PATIENT
ACKNOWLEDGEMENT**

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